2008-2009 DRAFT STATE HEALTH PLAN COMMENTS RECEIVED FROM

1. Gerald Harmon, MD – South Carolina Medical Association
2. Gray Maklary – Tuomey Healthcare System
3. Joe Mills – Accuray, Inc.
4. David Dunlap – Roper St. Francis Healthcare
5. Lynn Bailey – Lynn Bailey Associates
6. Virgil Alfaro, III, MD, Eric Jablon, MD, and John Kerrison, MD – Charleston Neuroscience Institute
7. Virgil Alfaro, III, MD – Retina Division of Charleston Neuroscience Institute
8. Tom Bradley – North Myrtle Beach
9. Kerry Ryan – Sunnyside Healthcare Commons
10. Rick Taylor – Georgetown Hospital System
11. Brian Cain – Chartwell Capital Company
12. J. Thornton Kirby – South Carolina Hospital Association
13. Sister Judith Ann Karam – Providence Hospital
14. Mac Leopard, MD – Thoracic and Cardiovascular Associates
15. Lanneau Lide, MD – South Carolina Heart Center
16. Micheal Biediger – Lexington Medical Center
17. Richard Baehr – Richard A. Baehr & Associates, Chicago
18. Douglas Bryant – The Bryant Company
19. Charles Beaman, Jr. – Palmetto Health
20. Elizabeth Fletcher – Spartanburg Regional Healthcare System
21. F. Del Murphy Jr. – Carolinas Healthcare System, Charlotte
22. Sam Tolbert – Strategic Directions
23. Judith Cullison – Presbyterian Healthcare, Charlotte
24. Valinda Rutledge – Bon Secours St. Francis Health System
25. Jane Pressley and Jim Van Hecke – Upstate South Carolina Recovery Center
26. J. Timothy Browne – Loris Healthcare System
27. Bruce Bailey – Georgetown Hospital System
28. Stuart Smith – Medical University of South Carolina
29. Andrea Brisbin – Trident Health System
30. Doug White – Grand Strand Regional Medical Center
31. Patricia "P.J." Johnson – Summerville Medical Center
32. Terry Gunn – Trident Health System
33. Mitchell Mongell – Colleton Medical Center
34. Timothy Rogers – South Carolina Home Care Association
35. Jac Upfield – South Carolina Department of Mental Health
36. Ronald Huffman – South Carolina Department of Social Services
37. Felicity Myers – South Carolina Department of Health and Human Services

#1
Gerald Harmon, MD – South Carolina Medical Association

From: "Gerald Harmon" <gamecockmd@aol.com>
To: <sheltolw@dhec.sc.gov>
CC: <todd@scmanet.org>
Date: 2/21/2008 11:15 PM
Subject: State Health Plan review

Les:

I reviewed our draft copy of the 2008-2009 SC Health Plan. I have no major comments or suggested revisions. There is a tiny typo on page I-4, third line of third paragraph where "CMA" is incorrect instead of "CMS" for the Center for Medicare and Medicaid Services.

Gerry Harmon

Gerald E. Harmon, MD, FAAFP

President, SC Medical Association

843-995-3580

#2
Gray Maklary – Tuomey Healthcare System

TUOMEY
HEALTHCARE SYSTEM

RECEIVED
FEB 25 2008
HEALTH PLANNING AND
SERVICES DEVELOPMENT

February 21, 2008

Mr. Les Shelton, Senior Planner
Division of Planning and CON
SCDHEC
2600 Bull Street
Columbia, SC 29201

Re: 2008 – 2009 State Health Plan Draft

Dear Mr. Shelton:

On page III-24, under the Region III narrative, it states under unusual characteristics that Sumter has a military hospital to provide health care services for the active duty and dependents residing in this region. Shaw AFB's inpatient hospital, except all OB services, closed in the late 90s/early 2000. Their OB inpatient services closed about 4 – 6 years ago. They no longer have an inpatient facility of any kind serving any of their active duty personnel. Tuomey has taken on most of their inpatient services, especially their OB services and they are the main reason we finally expanded our Nursery, Labor & Delivery and Post-partum capabilities in our most recently completed construction project. We ask that you remove this statement from the narrative. Thank you.

Sincerely,

Gray Maklary

Ms. Gray Maklary
Administrative Director, Facilities Planning

129 North Washington Street Sumter, South Carolina 29150
TEL: (803) 778-9000 FAX: (803) 778-9039 WEB: www.tuomey.com

#3
Joe Mills – Accuray, Inc.

From: "Joe Mills" <jmills@accuray.com>
To: <SHELTOLW@dhec.sc.gov>
Date: 2/26/2008 4:18 PM
Subject: CyberKnife Radiosurgery Systems

Mr. Shelton:

I have reviewed the Draft 2008-2009 South Carolina Health Plan and would like to comment on the Megavoltage Radiotherapy and Radiosurgery Section.

Stereotactic Radiosurgery was once limited to the Gamma Knife for treating some intra-cranial lesions and functional issues. With the introduction of CyberKnife and other LINAC based radiosurgery systems, there has been rapid growth in total body Radiosurgery. A full course of Radiosurgery requires only 1 to 5 treatments versus 30 to 40 for radiotherapy. Radiosurgery treatments require 1 to 2 hours to complete depending on tumor location, patient compliance, and complexity of the treatment plan. The typical LINAC based Radiosurgery System would provide 4 treatments per day, 5 days per week, 50 weeks per year or a maximum capacity of 1,000 treatments per year per unit. It is important to note that a single radiosurgery system can treat more patients per year than the average radiotherapy unit operating at its rated capacity of 7,000 treatments.

The SG-2 report on trends in Radiation Therapy predicts Radiosurgery procedures to grow 108% for brain cancers and 255% for body radiosurgery. The CyberKnife and other LINAC based Radiosurgery Systems are now treating lung, liver, pancreas, prostate and other body areas. Studies are underway to compare radiosurgery as an alternative to surgery for early stage lung cancers to take advantage of the accuracy and noninvasive treatments.

States that have CON requirements are incorporating language to recognize LINAC based radiosurgery as a growing modality to treat lesions anywhere in the body. The proposal to require a radiosurgery device to perform 4,000 treatments per year does not accurately reflect the actual usage of a LINAC based radiosurgery system. Radiosurgery does not replace Radiotherapy and should be considered as a new healthcare service. Radiosurgery provides a new treatment option to those patients that cannot be considered for surgery or traditional radiation therapy. Clinicians in South Carolina will petition to the state to add this new capability. If the plan does not adequately differentiate the actual radiosurgery treatment capacity then it will cause undue stress on the process.

Suggested Change: Within geographic areas or population zones, permit LINAC based radiosurgery programs to be developed. The needs criteria would be similar to standard radiation therapy but instead of 7,000 treatments per year as a capacity, use 900 treatments which more accurately reflect a full radiosurgery work load for a dedicated LINAC based Radiosurgery System.

I tried to call you today to discuss. Please call me if you would like additional information.

Thank you for considering my input.

Regards,

Joe Mills

Director, Corporate Accounts

ACCURAY INC

C 615 294 4224

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Visit www.accuray.com for more information

#4
David Dunlap – Roper St. Francis Healthcare

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HEALTHCARE

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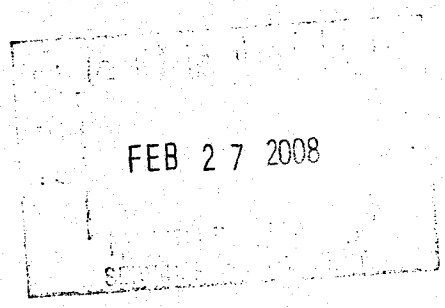
February 25, 2008



Mr. Les Shelton, Division of Planning and Certificate of Need
S.C. Department of Health and Environmental Control and
The S.C. State Health Planning Committee
c/o 1777 St. Julian Place Suite 201
Columbia, SC 29204

Dear Mr. Shelton and Committee Members:

Re: Comments on the Draft 2008-2009 State Health Plan

I appreciate the opportunity to provide comments regarding the Draft State Health Plan. On behalf of Roper St. Francis Healthcare (Roper Hospital, Bon Secours St. Francis Hospital, Roper Berkeley Ambulatory Surgery Center, Roper West Ashley Ambulatory Surgery Center, Roper St. Francis Home Health Care and other affiliated facilities), please give consideration to the remarks below bolded by section:

General Hospitals

Roper St. Francis Healthcare (RSFH) supports the revised methodology for calculating bed need; however, as has been the case nationwide, specialty hospitals are a major concern as a threat to existing community hospitals. Please consider an additional criterion whereby any new hospital must be a general hospital, provide Level III emergency services, accept government insurance, and provide un-reimbursed services for indigent patients at a percentage that meets other hospitals in the service area.

Furthermore, all metropolitan service areas with multiple counties should be treated in the same manner as it relates to county bed need. Only 5 of the 46 counties are currently combined (Berkeley/Charleston/Dorchester counties and Orangeburg/Calhoun counties), as the Committee voted to "un-do" the combination of Richland and Lexington counties as originally drafted. The State Health Plan needs one policy consistently applied whereby each county is considered separately.

Cardiovascular Care

The American College of Cardiology (ACC) and the American Heart Association (AHA) state that performance of elective PCI in a setting without immediately available on-site cardiac surgery potentially compromises patient safety and is not recommended. There are no ACC/AHA established criteria for patient selection or guidelines for performance of elective PCI without surgical back up. For these reasons, RSFH is against allowing participation in the C-PORT study to perform elective PCI at hospitals without cardiac surgery capability.

Megavoltage Radiotherapy & Radiosurgery

Two major changes were proposed in the standards for radiosurgery equipment as it relates to the Gamma Knife. First, the capacity for full-time operation was reduced from 5 days to 3 days (500 procedures to 300 procedures) with no stated explanation or rationale. In addition, the current designated service area consisting of the entire state was omitted despite the limited number of eligible cases. Upon examination of the one existing provider, which demonstrated low utilization (48% in 2006), RSFH questions the prudence of these proposed changes and opposes both of these revisions in the Draft Plan.

Please note that stereotactic radiosurgery is not limited to the Gamma Knife, but also includes the CyberKnife and Brain Lab. The capacity of the CyberKnife is approximately 900 annual fractions/treatments as provided by Accuray, the sole equipment vendor. The Draft Plan included the CyberKnife in the radiotherapy category and uses a capacity of 4,000 annual treatments. RSFH requests both the categorization and capacity be corrected to reflect the lower number of cases that can safely and efficiently be treated on the stereotactic radiosurgery equipment.

In addition, all radiosurgery modalities (Gamma Knife, CyberKnife, Brain Lab) should be considered before new services are approved. We recommend the state be divided into geographic areas, and intra-cranial and extra-cranial treatments be reported separately on both the Joint Annual Reports and in the utilization chart in the State Health Plan.

Finally, the utilization chart on page 11-61 for linear accelerators would be more useful if the treatments per accelerator were changed to a total # of treatments and a column added that lists the total number of patients treated.

Positron Emission Tomography and PET/CT

Standard #1 states, "Applicants for a freestanding PET service not operated by a hospital must document referral agreements from health care providers that would justify the establishment of such services". In order to substantiate the applicant's volume projections please consider an additional requirement whereby the applicant must specify the referral source of those patients and from which current provider those referrals will be redirected.

Magnetic Resonance Imaging

RSFH understands the rationale for removing the criteria for MRI scanners and can support this decision.

Ambulatory Surgical Facilities

The new standard #11 requires an applicant to commit to accept Medicare and Medicaid patients, as well as provide un-reimbursed services to indigent patients at a "...percentage which is comparable to other health care facilities in the service area". As surgery centers as a whole do not see the volume of indigent care that hospitals do for a number of reasons, (namely because procedures are predominantly elective and of a non-emergent nature) RSFH requests that the language "comparable to other health care facilities" be changed to "comparable to other ambulatory surgery facilities in the service area".

RSFH requests that the Department re-instate its utilization surveys of all existing hospitals and freestanding surgery centers in the county when an application for a new center is received, as this will serve as a useful aid in the determination of capacity and need, neither of which is identified by the State Health Plan. The survey results could also assist in evaluating the potential adverse effects of service duplication.

Emergency Hospital Services

While RSFH supports the drafted standards we feel strongly that an additional standard be created whereby the applicant must demonstrate need, document where the potential patients will come from, and address why they are not being adequately served by existing services in the area.
In addition, RSFH supports each of the following sections as drafted: obstetrical and neonatal services, rehabilitation beds, long term care hospitals, critical access hospitals, community psychiatric beds, home health agencies, and nursing homes.

Again, thank you for your consideration of these comments relative to important health planning issues. Should you need to reach me, please contact me at 843-724-2915.

Sincerely,

David L. Dunlap, FACHE
President and Chief Executive Officer

#5
Lynn Bailey – Lynn Bailey Associates

LYNN BAILEY ASSOCIATES

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February 28, 2008

RE: Draft 2008-09 South Carolina Health Plan

Gerald Wilson, MD, Chair
Edward Tinsley, III, Vice Chair
Les Shelton, Staff
SC State Health Planning Committee
SC DHEC
2600 Bull Street
Columbia, SC 29201

Dear Dr. Wilson, Mr. Tinsley and Mr. Shelton:

Please consider this letter my comments on the Draft 20008-09 SC State Health Plan. The State Health Plan is key to making South Carolina's healthcare system more rational and hopefully more efficient and effective. The purpose of South Carolina's CON program is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services that will best serve public needs, and ensure that ***high quality services are provided*** in health facilities in this State.

Emphasis in the Plan and by the CON staff on quality and patient safety has been secondary to cost and unnecessary duplication of services. **I believe it is time that quality and patient safety receive greater emphasis in the Plan and in the CON review process.** Recently the Department (DHEC), the Center for Medicare and Medicaid Services (CMS) and SC Hospital Association (SCHA) have publically released information on hospital acquired infections, patient safety, and hospital (and nursing home) quality. These data are released to the public primarily through the following websites: scdhec.gov, medicare.gov and mySChospital.org. I wish that cost data were as readily available.

The growth of publically available quality data makes it imperative the Health Plan directly address these quality and patient safety issues in the development of its health facility and service standards and criteria. Currently it is included in the State Health Plan and CON review as sort of an after thought, tagged on to end of Part B questionnaire and seldom mentioned in specific standards or review criteria. If we value quality, we measure it, and use these measures to encourage high quality providers.

Why should we expand mediocre services before we make them better or safer? If a new or existing provider with a track record of high quality can provide a service currently provided but with mediocre quality indicators, the proposed provider should receive a CON for that service without having to face a challenge of "unnecessary duplication". Providers with below the statewide average in critical quality and patient safety measures should not receive a CON to

expand any of their services or have standing to challenge another provider willing to provide high quality or safer care. Providers need to know that poor quality care invites other providers to step up and fill the quality gap. This is the competition that makes healthcare better and safer.

The second issue I believe to be important for the Plan to address is the shortage of key labor resources such as nursing and technical staff. Major facility or health services expansions should require extensive documentation of current staffing ratios and future plans to sustain or improve those ratios. There is substantial health services research to support the linkage of adequate (in terms of quantity and quality) staffing to high quality and safe care. I am asking the State Health Planning Committee to undertake a study to determine how best to incorporate nurse and technical staffing information into future State Health Plans. Just because it is hard and data are currently limited, doesn't mean South Carolina shouldn't attempt to develop the data and the standards to make high quality care our goal.

Certificate of need is how South Carolina rationalizes its healthcare resources. It is the public's only opportunity for oversight and accountability in our expensive and fragmented system. The Plan is an important public policy statement. It should reflect current and future conditions and expectations by outlining and promoting desired quality and patient safety measures.

Professional disclaimer: I offer my comments based on my 25+ years of working in health planning and CON in South Carolina. These are my own thoughts and suggestions. They are not made on behalf of any client. Thank you.

Sincerely,

Lynn Bailey

Lynn Bailey
Healthcare Economist

#6

Virgil Alfaro, III, MD, Eric Jablon, MD, and John Kerrison, MD – Charleston Neuroscience Institute

CHARLESTON NEUROSCIENCE INSTITUTE
RETINA CONSULTANTS
RETINA, MACULA, VITREOUS, NEURO-OPHTHALMOLOGY
D. VIRGIL ALFARO, III, M.D. • ERIC P. JABLON, M.D. • JOHN B. KERRISON, M.D.

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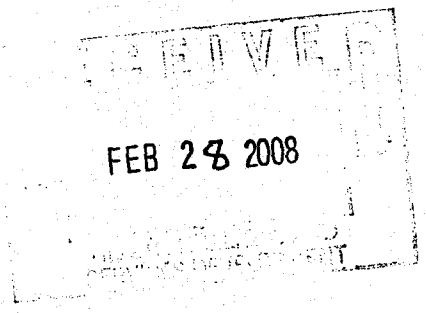
February 27, 2008



Mr. Les Shelton, Senior Planner
Bureau of Health Facilities & Services Development
SC DHEC
2600 Bull Street
Columbia, SC 29201

Dear Mr. Shelton:

Please forward these comments on the Draft 2008-2009 South Carolina Health Plan to the State Health Planning Committee.

The Draft Plan appears to require new facilities to meet a different standard than existing facilities. The Plan should require that all providers adhere to the same standards. It appears to assume that there is something wrong with a new provider. In fact, a new Ambulatory Surgery Facility could provide services that are more accessible and affordable than the existing facilities. This standard does not prohibit existing facilities from adding several additional operating suites. This standard does not provide a level playing field for the same services and can be detrimental to the hospital and/or other potential providers. It also seems to discriminate against new providers and is unfair.

The following standard from pages II-73-74 of the Draft Plan confirms this discriminatory policy toward new providers:

(9) Before an application for a new Ambulatory Surgery Facility can be accepted for filing, all existing ASF's in the county where the proposed facility is to be located must have been licensed and operational for an entire year, and submitted data on the Department's annual questionnaire to allow for a determination of their utilization. The data will not be prorated or projected into the future but based on actual utilization. For purposes of this standard, endoscopy suites are considered separately from other operating rooms. Endoscopy-only ASF's do not impact other ASF's. Before additional licensed endoscopy suites can be added in a county, all ASF's with licensed endoscopy suites must have had these suites licensed and operational for one year to allow for a determination of the utilization of the endoscopy providers.

Recommendation: This standard should be deleted.

Ongoing Clinical Trials

Alimera Sciences
Fluocinolone Acetonide for Diabetic Macular Edema

NIH - National Eye Institute
Intravitreal Triamcinolone for Macular Edema

The following standard from page II-74 also confirms this discriminatory policy against new providers:

(10) In no case can more than one new ASF in a county be approved at a single time. The approval of a new ASF in a county does not preclude an existing facility from applying to expand its number of operating rooms and/or endoscopy suites.

This standard allows for an existing ASF to expand the number of operating suites at any time. In fact two or three existing ASF's could apply to expand at the same time; however, two new facilities could not be approved even if they were at opposite ends of a county . For example, an ASF could not be approved in the town of York, SC and the town of Fort Mill, SC at the same time even though they are at opposite ends of a rapidly growing county. These two communities are more than 20 miles apart. A new ASF could be approved in both Fort Mill and three miles east into Lancaster County on the same highway. This standard seems to be incongruent with the expansion of new medical facilities and technology.

Recommendation:

This standard should be deleted.

Sincerely,

D. Virgil Alfaro, III, M.D. Eric P. Jablon, M.D. John B. Kerrison, M.D.

#7

Virgil Alfaro, III, MD – Retina Division of Charleston Neuroscience Institute

Retina Division of Charleston
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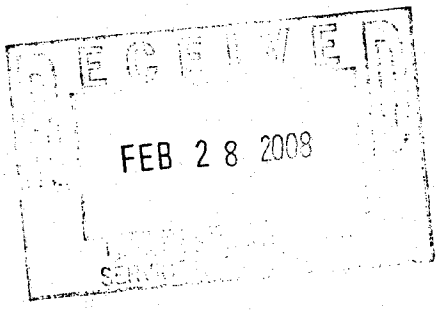
Charleston, SC 29414



February 25, 2008

Dr. Gerald A. Wilson, Chairman
State Health Planning Committee
SC DHEC
2600 Bull Street
Columbia, SC 29201

Dear Dr. Wilson:

Thank you for the opportunity to make comments on the Draft 2008-2009 South Carolina Health Plan. After reviewing the Draft Plan, the comments are submitted for your review on the following.

AMBULATORY SURGERY FACILITY SECTION OF THE PLAN

According to Section 44-7-110 through Section 44-7-340 of the South Carolina Code of Laws as amended, the purpose of Certificate of Need is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve the public needs, and ensure that high quality services are provided in health facilities in South Carolina.

Based on the above purposes, the following comments are presented for your consideration.

The following standards on pages II-73 -74 in the Draft Plan should be amended for the following reasons:

(7) **All new Certificate of Need approvals by the Department will not restrict the specialties of ASF'S. However, it is the position of the Department that Ambulatory Surgery Facilities open to and equipped for all surgical specialties will better serve the community than those targeted toward a single specialty or group of practitioners. For an ASF approved to only perform endoscopic procedures, another CON would be required before the center could provide other surgical specialties. For an ASF approved only for a single specialty, a CON is required before the facility can provide other surgical specialties.**

For the establishment of a health facility and service which will best serve the public needs, this standard should be revised to allow for specialty ambulatory surgery centers. Retinal disease accounts for 70% of South Carolina patients who are legally blind, defined as vision of 20/200 or less. The

needs of the visually impaired are well-defined by the American Disabilities Act and other architectural and planning documents that suggest ways to better serve these patients. No existing ambulatory surgery center in South Carolina meets the needs of these patients and the standard should be changed to allow for ASC s dedicated to ophthalmic surgery

Locally, nationally, and internationally a standard has been defined that shows improved quality and decreased cost by centers dedicated to eye care and eye surgery. Equipment dedicated for ophthalmology use is delicate and technologically advanced, requiring a nursing and administrative staff dedicated to eye care.

Many of these patients undergo vitreous and retina surgery. In the state of South Carolina no center exists for the treatment of ocular melanoma, the most common primary tumor of the eye. Advanced and specialized radioactive plaques and the use of specially calibrated ophthalmic lasers remain the standard for treating this disease. Also, endoscopic ophthalmic surgery is non-existent in South Carolina. Endoscopic surgery of the vitreous cavity and retina would provide a more advanced means of treating retinal disease in the setting of severe anterior segment opacities.

The surgical needs for this group of primarily elderly patients differs from other surgery. The eye is very delicate and eye surgery revolves around this one specific organ requiring specialized techniques from experienced opthalmological staff. An ASF specializing in opthalmological procedures only would be able to have multiple lasers for treating various problems of the eye, such as the Argon and Selective Laser Trabeculoplasty (SLT) for treating glaucoma, the Opal or Photodynamic Therapy Laser (PDT) laser for retinal disease, the Yag laser for post-cataract capsule treatment and glaucoma, as well as the bladeless IntraLase laser and Visx Excimer laser for LASIK procedures. Ambulatory surgeryfacilities that do not specialize in eye surgery cannot have this needed up-to-date equipment for patients requiring eye surgery. Provision of a standard in the State Health Plan allowing for a single specialty eye surgery center would benefit the citizens of South Carolina as follows:

A) The ASF staff would be dedicated to serve patients having eye surgery,
B) the facility would be designed to serve the legally blind patient,
C) the overall health care costs would be less in a specialty center,
D) lasers and other eye surgery equipment would be located in a designated facility, and
E) the chance of infections from bacteria harbored at other body sites would be lessened.

This is not a new concept, as DHEC previously approved the Columbia Eye Surgery Center in Columbia for eye surgery only procedures and that ASF has elected to continue operating with a license restricted only to opthalmological surgical procedures in order to benefit its patients.

RECOMMENDATION:

This standard should be amended to allow for the establishment of facilities that will best serve the public needs and ensure that high quality services are provided in health facilities in South Carolina. The Certificate of Need review staff would have the prerogative to review the need for such a facility based on evidence provided by the applicant. The standard as currently written is a broad statement prohibiting a single specialty ambulatory surgery center from being established with no evidence that this serves the best needs of the public. The following change is recommended:

(7) For an ASF approved only for a single specialty, another CON is required before the facility can provide other surgical specialties. For an ASF approved to only perform

endoscopic procedures, another CON would be required before the center could provide other surgical specialties.

The standard below from pages II-73-74 should be deleted.

(9) Before an application for a new Ambulatory Surgery Facility can be accepted for filing, all existing ASF's in the county where the proposed facility is to be located must have been licensed and operational for an entire year, and submitted data on the Department's annual questionnaire to allow for a determination of their utilization. The data will not be prorated or projected into the future but based on actual utilization. For purposes of this standard, endoscopy suites are considered separately from other operating rooms. Endoscopy-only ASF's do not impact other ASF's. Before additional licensed endoscopy suites can be added in a county, all ASF's with licensed endoscopy suites must have had these suites licensed and operational for one year to allow for a determination of the utilization of the endoscopy providers.

This standard has potential to cause serious delays for the establishment of an ambulatory surgery facility whether proposed by hospitals or other entities. This standard does not promote cost containment as it prohibits development of needed services to the public for years.

This standard prevents DHEC from accepting an application for an Ambulatory Surgery Facility until all existing ASF's in the county have been licensed and operational for a year. For example, if a new ASF were approved for a CON in March, 2006 and the facility would have to be constructed, it would probably be April or May, 2007 before it was completed. Then the facility would have to be licensed and operational for another year. Because DHEC only requests data from a facility once a year (January or February), a full year of utilization information from the facility would not be available in January 2008, since only about eight months of data would exist at that time. Under this standard, DHEC would have the required data in January 2009, and it would be at least February 2009 before another applicant could apply for a CON for an ASF, followed by approximately six more months to receive a decision. In this case, a CON may be issued in late 2009, which is at least three years since the first ASF was approved. If the first ASF were appealed, the process would take considerably longer, at least one or two years longer.

This built in delay could be very detrimental in getting a needed service established in a county. It would not be promoting cost containment and could cause an increase in health care costs by delaying a less costly alternative. In fact, it could even prevent the establishment of a specific type of ASF. This standard neither weighs the merits of adding another ASF nor considers the growth of the population in a county, nor does it consider the distance from one facility to another. For example, an ASF could have been approved the southern part of Horry County and another applicant could have wanted one in Loris, SC, which is at the other end of the county. The first one would have no impact on the the proposed second facility as they are different market areas and located more than 30 miles away and on the other side of a high traffic, high growth area. This standard may result in an increase in health care costs and prevent the development of lower cost alternatives in a timely manner. The staff of DHEC should have the prerogative of reviewing applications and then making a determination as to whether or not a proposal is warranted or needed. This standard effectively becomes a moratorium on the addition of any ASF for several years. The standard states that the data submitted by the facilities will be used for a determination of their utilization. What does this mean in relationship to a proposed new

facility? Will the impact of this newest provider be analyzed to determine the impact on the existing providers after this several year delay? If two facilities are at opposite ends of a large county with a high growth area, how will this promote cost containment and the guidance of health care facilities to best serve the public needs?

RECOMMENDATION:

This standard should be deleted to allow for the establishment of facilities in a timely manner that will best meet the public need and ensure that high quality services are provided in health facilities. This standard also effectively ties the hands of the DHEC Certificate of Need staff regardless of the need or demand for another facility. Even though a new facility is currently prohibited from being developed by this standard, additional operating rooms may be added to existing facilities, further promoting maldistribution of resources in a county. One facility may effectively establish a monopoly on ambulatory surgery facilities in a county, which could negatively impact hospitals or other providers.

The standard below from page II-74 should be deleted.

(10) In no case can more than one new ASF in a county be approved at a single time. The approval of a new ASF in a county does not preclude an existing facility from applying to expand its number of operating rooms and/or endoscopy suites.

This standard prohibits the needed approval of a new ASF in a county when another facility is being proposed in a different more distant location in the same county. For example, a new ASF is currently allowed CON approval across the street from another proposed ASF if it is located in a different county, which is an occurrence that may take place in any rapidly developing metropolitan area of South Carolina. However, another provider may not build a new facility but a competitor could build additional rooms to an existing ASF. This standard should be deleted, which would allow DHEC Certificate of Need staff to have the discretion to review and approve needed facilities rather than be bound by an oppressive unrealistic standard

RECOMMENDATION:

This standard should be deleted.

Thank you considering these comments and recommendations.

Sincerely,

Virgil Alfaro, M.D.

#8
Tom Bradley – North Myrtle Beach

Tom T. Bradley
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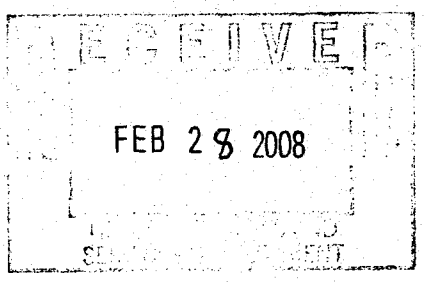
N. Myrtle Beach, SC 29582

February 26, 2008



Gerald A. Wilson, M.D., Chairman
State Health Planning Committee
SC Department of Health & Environmental Control
2600 Bull Street
Columbia, SC 29201

Dear Dr. Wilson:

According to Section 44-7-110 through Section 44-7-340 of the South Carolina Code of Laws as amended, the purpose of Certificate of Need is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve the public needs, and ensure that high quality services are provided in health facilities in South Carolina.

Based on the above purposes, the following comments on the Ambulatory Surgery Section of the Draft Plan are presented for your consideration.

The following standards on pages II-73 -74 in the Draft Plan should be amended for the following reasons:

(7) **All new Certificate of Need approvals by the Department will not restrict the specialties of ASF'S. However, it is the position of the Department that Ambulatory Surgery Facilities open to and equipped for all surgical specialties will better serve the community than those targeted toward a single specialty or group of practitioners. For an ASF approved to only perform endoscopic procedures, another CON would be required before the center could provide other surgical specialties. For an ASF approved only for a single specialty, a CON is required before the facility can provide other surgical specialties.**

For the establishment of a health facility and service which will best serve the public needs, this standard should be revised to allow for specialty ambulatory surgery centers. Retinal disease accounts for 70% of South Carolina patients who are legally blind, defined as vision of 20/200 or less. The needs of the visually impaired are well-defined by the American Disabilities Act and other architectural and planning documents that suggest ways to better serve these patients. No existing ambulatory surgery center in South Carolina meets the needs of these patients, and the standard should be changed to allow for ASC s dedicated to ophthalmic surgery.

Locally, nationally, and internationally a standard has been defined that shows improved quality and decreased cost by centers dedicated to eye care and eye surgery. Equipment dedicated for ophthalmology use is delicate and technologically advanced, requiring a nursing and administrative staff dedicated to eye care.

Many of these patients undergo vitreous and retina surgery. In the state of South Carolina no center exists for the treatment of ocular melanoma, the most common primary tumor of the eye. Advanced and specialized radioactive plaques and the use of specially calibrated ophthalmic lasers remain the standard for treating this disease. Also, endoscopic ophthalmic surgery is non-existent in South Carolina. Endoscopic surgery of the vitreous cavity and retina would provide a more advanced means of treating retinal disease in the setting of severe anterior segment opacities.

The surgical needs for this group of primarily elderly patients differs from other surgery. The eye is very delicate and eye surgery revolves around this one specific organ requiring specialized techniques from experienced opthalmological staff. An ASF specializing in opthalmological procedures only would be able to have multiple lasers for treating various problems of the eye, such as the Argon and Selective Laser Trabeculoplasty (SLT) for treating glaucoma, the Opal or Photodynamic Therapy Laser (PDT) laser for retinal disease, the Yag laser for post-cataract capsule treatment and glaucoma, as well as the bladeless IntraLase laser and Visx Excimer laser for LASIK procedures. Ambulatory surgery facilities that do not specialize in eye surgery cannot have this needed up-to-date equipment for patients requiring eye surgery. Provision of a standard in the State Health Plan allowing for a single specialty eye surgery center would benefit the citizens of South Carolina as follows:

A) The ASF staff would be dedicated to serve patients having eye surgery;
B) the facility would be designed to serve the legally blind patient;
C) the overall health care costs would be less in a specialty center;
D) lasers and other eye surgery equipment would be located in a designated facility; and
E) the chance of infections from bacteria harbored at other body sites would be lessened.

This is not a new concept, as DHEC previously approved the Columbia Eye Surgery Center in Columbia to be restricted for eye surgery only procedures, and that ASF has elected to continue operating with a license restricted only to opthalmological surgical procedures in order to benefit its patients.

RECOMMENDATION:

This standard should be amended to allow for the establishment of facilities that will best serve the public needs and ensure that high quality services are provided in health facilities in South Carolina. The need for such a facility should be based on evidence provided by the applicant. The standard as currently written is a broad statement prohibiting a single specialty ambulatory surgery center from being established with no evidence that this serves the best needs of the public. The following change is recommended:

(7) For an ASF approved only for a single specialty, another CON is required before the facility can provide other surgical specialties. For an ASF approved to only perform endoscopic procedures, another CON would be required before the center could provide other surgical specialties.

The standard below should be deleted.

> **(9) Before an application for a new Ambulatory Surgery Facility can be accepted for filing, all existing ASF's in the county where the proposed facility is to be located must have been licensed and operational for an entire year, and submitted data on the Department's annual questionnaire to allow for a determination of their utilization. The data will not be prorated or projected into the future but based on actual utilization. For purposes of this standard, endoscopy suites are considered separately from other operating rooms. Endoscopy-only ASF's do not impact other ASF's. Before additional licensed endoscopy suites can be added in a county, all ASF's with licensed endoscopy suites must have had these suites licensed and operational for one year to allow for a determination of the utilization of the endoscopy providers.**

This standard has potential to cause serious delays for the establishment of an ambulatory surgery facility whether proposed by hospitals or other entities. This standard does not promote cost containment as it prohibits development of needed services to the public for years.

This standard prevents DHEC from accepting an application for an Ambulatory Surgery Facility until all existing ASF's in the county have been licensed and operational for a year. For example, if a new ASF were approved for a CON in March 2006 and the facility would have to be constructed, it would probably be April or May 2007 before it was completed. Then the facility would have to be licensed and operational for another year. Because DHEC only requests data from a facility once a year (January or February), a full year of utilization information from the facility would not be available in January 2008, since only about eight months of data would exist at that time. Under this standard, DHEC would have the required data in January 2009, and it would be at least February 2009 before another applicant could apply for a CON for an ASF, followed by approximately six more months to receive a decision. In this case, a CON may be issued in late 2009, which is at least three years since the first ASF was approved. If the first ASF were appealed, the process would take considerably longer, at least one or two years longer.

This built in delay could be very detrimental in getting a needed service established in a county. It would not be promoting cost containment and could cause an increase in health care costs by delaying a less costly alternative. In fact, it could even prevent the establishment of a specific type of ASF. This standard neither weighs the merits of adding another ASF nor considers the growth of the population in a county, nor does it consider the distance from one facility to another. For example, an ASF could have been approved for the southern part of Horry County and another applicant could have proposed one in Loris, SC, which is at the other end of the county. The first one would have no impact on the the proposed second facility as they are different market areas and located more than 30 miles away and on the other side of a high traffic, high growth area. This standard may result in an increase in health care costs and prevent the development of lower cost alternatives in a timely manner. The staff of DHEC should have the prerogative of reviewing applications and then making a determination as to whether

or not a proposal is warranted or needed. This standard effectively becomes a moratorium on the addition of any ASF for several years. The standard states that the data submitted by the facilities will be used for a determination of their utilization. What does this mean in relationship to a proposed new facility? Will the impact of this newest provider be analyzed to determine the impact on the existing providers after this several year delay? If two facilities are at opposite ends of a large county with a high growth area, how will this promote cost containment and the guidance of health care facilities to best serve the public needs?

RECOMMENDATION:

This standard should be deleted to allow for the establishment of facilities in a timely manner that will best meet the public need and ensure that high quality services are provided in health facilities. This standard also effectively ties the hands of the DHEC Certificate of Need staff regardless of the need or demand for another facility. Even though a new facility is currently prohibited from being developed by this standard, additional operating rooms may be added to existing facilities, further promoting maldistribution of resources in a county. One facility may effectively establish a monopoly on ambulatory surgery facilities in a county, which could negatively impact hospitals or other providers.

The standard below should be deleted.

> **(10)In no case can more than one new ASF in a county be approved at a single time. The approval of a new ASF in a county does not preclude an existing facility from applying to expand its number of operating rooms and/or endoscopy suites.**

This standard prohibits the needed approval of a new ASF in a county when another facility is being proposed in a different more distant location in the same county. For example, a new ASF is currently allowed CON approval across the street from another proposed ASF if it is located in a different county, which is an occurrence that may take place in any rapidly developing metropolitan area of South Carolina. However, another provider may not build a new facility but a competitor could build additional rooms to an existing ASF. This standard should be deleted, which would allow DHEC Certificate of Need staff to have the discretion to review and approve needed facilities rather than be bound by an onerous, unrealistic standard.

RECOMMENDATION:

This standard should be deleted.

Thank you,

Tom Bradley

#9
Kerry Ryan – Sunnyside Healthcare Commons

February 25, 2008

FEB 28 20

Gerald A. Wilson, M.D., Chairman
S.C. State Health Planning Committee
SC DHEC
2600 Bull Street
Columbia, SC 29201

Dear Dr. Wilson:

Thank you for considering the following comments. Because a new State Health Plan is only required to be developed every two years, we sincerely hope that the Planning Committee will incorporate these ideas into the final version of the 2008-2009 South Carolina Health Plan. If a revised Plan is not developed until 2010 using the same methodology and historical utilization, needed services may not be projected in a timely manner and the staff of DHEC will not be able to approve projects that may be needed to increase access and alleviate problems in the existing health care facilities. The following suggested amendments will enable needed services to be developed in a more expedient manner.

Please consider the following as comments on the Draft 2008-2009 South Carolina Health Plan.

PSYCHIATRIC BEDS IN THE DRAFT 2008-2009 SOUTH CAROLINA HEALTH PLAN

Access to community psychiatric beds is a problem in many areas of South Carolina. In the psychiatric service area of Allendale, Beaufort, Hampton and Jasper Counties with a current population of approximately 200,000 people, there are only 14 psychiatric beds. These 14 psychiatric beds are located in Beaufort which is 60 miles from Allendale and 43 miles from Hilton Head, SC. The other four hospitals in this service area do not have any psychiatric beds to serve the population. This shortage of mental health services can aggravate the problems of patients in crisis appearing in emergency rooms. Hospital emergency departments are among the least appropriate and most expensive places for patients in emergency crisis. The ER gives psychiatric medications, but is not staffed or equipped to provide comprehensive psychiatric care.

To help alleviate the problem of access to psychiatric beds and because the number of psychiatric beds in South Carolina has been reduced over the past several years, we are recommending that the Plan be amended to allow for an increase in the number of psychiatric beds. We suggest the following amendment to the Plan on page II-84, paragraph four:

A psychiatric unit or freestanding psychiatric facility should be allowed contain a minimum of 30 beds in order to be more economically feasible. An existing unit of less than 30 beds would be allowed to add additional beds in order to increase the size of the unit to 30 beds in order to take

advantage of the economies of scale of these specialized units. If the number of beds needed is less than 30, then up to a total of 30 beds could be approved. The applicant must document the need for additional beds based on the economics of construction, historical and projected utilization, floor plan layouts, projected population growth and any other factors that could justify this increased need. Because these facilities will only serve a limited population group, it is necessary to allow for enough beds to make an economical unit.

REHABILITATION BEDS IN THE DRAFT 2008-2009 SOUTH CAROLINA HEALTH PLAN

The average occupancy rate for Rehabilitation facilities was 73.2% in 2006 which is exceptionally high considering that the average bed size was 40.7 beds. The methodology reflected in the Draft Plan is a considerable improvement over what was formerly used in previous State Health Plans. By using 75% of the statewide beds, this has increased the number of beds needed; however, these are still small numbers and may not allow for enough beds to make an economical unit. In the general hospital bed need section, if a need is indicated for just one additional bed, general hospitals can apply for up to thirty (30) beds to make an economical unit. This same concept should apply to rehabilitation beds. For example, if a need is indicated for 20 beds, a facility should be able to apply for up to 30 beds to ensure that there are enough beds/patients to justify the hiring of enough therapists and other staff for this specialized service.

We would suggest that a paragraph be added to page II-104 of this section of the Plan as follows:

A rehabilitation unit should be allowed to contain a minimum of 30 beds in order to be more economically feasible. An existing unit of less than 30 beds would be allowed to add additional beds in order to increase the size of the unit to 30 beds in order to take advantage of the economies of scale of these specialized units. The facility will justify the need for the additional beds considering the population growth, historical and projected utilization, floor plan layouts and other factors that could justify this increased need. Because these facilities will only serve a limited population group, it is necessary to allow for enough beds to make an economical unit.

Thank you for allowing us to provide input to the State Health Planning Committee.

Sincerely,

Kerry J. Ryan
Managing Partner

#10
Rick Taylor – Georgetown Hospital System

GEORGETOWN
HOSPITAL SYSTEM

February 25, 2008

RECEIVED
FEB 28 2008

SC State Health Planning Committee
South Carolina Department of Health and Environmental Control
Division of Planning and Certification of Need
2600 Bull Street
Columbia, South Carolina 29201

To Whom It May Concern:

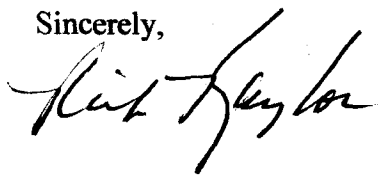
On behalf of the Georgetown Hospital System, I would like to make the following recommendations for the revision of the SC State Health Plan:

- Maintain the revised methodology for calculating bed need as presented in the current draft.
- There should be criteria in the Plan requiring that any new hospital must be a general hospital, provide at least Level III emergency services, accept all governmental insurance, and provide un-reimbursed services for patients at a percentage that meets or exceeds other hospitals in the service area.
- Revise Standard (#3) to read: For a new facility, the applicant must document where the potential patients for the facility will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. That documentation and projections of shifts must be shared with existing providers of surgical services in the county, and the applicant must provide documentation that has occurred. For an existing facility seeking expansion, the applicant must provide patient origin information on the current facility.
- Revise Standard (#6) to read: "The applicant must document the potential impact that the proposed new ASF or expansion will have upon existing service providers and referral patterns. To validate the projected impact, DHEC will survey all existing hospitals and free standing ASFs in the county concerning existing capacity and need. The results of these surveys will be a factor in evaluating possible adverse effects of duplication of service."
- Revise Standard (4) to read: A Certificate of Need is required to convert LTCH beds to general acute care beds, rehab beds, or psych beds.
- Create a new standard: A hospital which desires to be designated as an LTAC and has been awarded a CON for that purpose, must be certified as an LTAC by CMS within 24 months of accepting its first patient, or the CON issued to that hospital for that purpose shall be revoked. That entity which has had its CON revoked shall not have the authority to operate as a general acute care hospital.

- Create a new standard: An acute care hospital which has been awarded a CON to convert acute care beds for use in creating an LTAC, may again use its beds for acute care regardless of bed need within the county. If it is unable to acquire CMS certification as an LTAC, or if it no longer wishes to operate as an LTAC at that time, the hospital beds will revert to the official inventory of beds within that hospital.
- Georgetown Hospital System recommends the Radiotherapy section be segmented to reflect the standard services and the more specialized techniques and modalities.
- The planning capacity of 4,000 annual treatments for a Cyberknife is too high. The planning capacity should be reduced to 900 annual treatments.
- Revise Standard (4) B pertaining to a new provider's application for equipment to read: An applicant, whether the expansion occurs at the existing site or at an alternate location in the service area, must project that the proposed service will perform a minimum number of treatments equal to 50 percent of capacity annually within three years of initiation of services, without reducing the utilization of the existing machines in the service area below the 80 percent threshold. The applicant must document where the potential patients for this new service will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. Letters of support from referring physicians, with expected annual referral volumes, must be included.
- Georgetown Hospital System recommends adding the following statement to the radiotherapy section on page II-60, "Specialized radiotherapy techniques and modalities such as total body irradiation, IMRT, and Cyberknives may have an adverse impact on the utilization of existing standard linear accelerators."
- Georgetown Hospital System supports participation in the C-Port study of PCI without on-site cardiac surgery if the hospital meets the criteria for participation. The State Health Plan should allow upon receipt of a CON, a hospital to participate in the C-Port study for the duration of the study rather than the 3 years as specified in the plan. The State Health Plan should support hospitals conducting clinical research which might benefit the health of the citizens of our state. We believe DHEC should develop a mechanism for allowing appropriate clinical research within hospitals and which allows appropriate access for interested hospitals to become involved in clinical trials which could benefit the citizens in the communities.

Thank you for your time and for your consideration of the above referenced recommendations.

Sincerely,



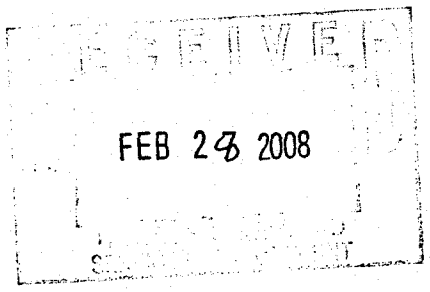
Rick Kaylor, FACHE
Chief Planning & Development Officer

#11
Brian Cain – Chartwell Capital Company

Chartwell Capital Company, LLC
30 Ellenita Drive
Hilton Head Island, SC 29926
843-342-4915

February 25, 2008

Gerald A. Wilson, M.D., Chairman
S.C. State Health Planning Committee
SC DHEC
2600 Bull Street
Columbia, SC 29201



Dear Dr. Wilson:

Please consider the following as comments on the Draft 2008-2009 South Carolina Health Plan. I appreciate your taking the time to review these two proposals which could make these needed services more accessible to the citizens of South Carolina.

COMMENTS ON THE PSYCHIATRIC BED NEED SECTION OF THE DRAFT 2008-2009 SOUTH CAROLINA HEALTH PLAN

Pages II-84-89 of the Draft Plan outline the needs for Community Psychiatric Beds throughout South Carolina. Access to community psychiatric beds is a problem in many areas of South Carolina. There is a shortage of services for the mentally ill and general hospitals must meet the challenge of caring for sometimes aggressive psychiatric patients. Much of this interaction occurs in overcrowded hospital emergency departments. Often, emergency rooms are the last resort for psychiatric patients in crisis and some patients are so out of control and aggressive that mental health facilities will not take them. Hospitals have even had to call the police for help. The ER staff give psychiatric medications, but are not trained to provide comprehensive psychiatric care. Hospital emergency departments are among the least appropriate and most expensive places for patients in emergency crisis. Yet these departments are where police, families, nursing homes and others routinely take people who are agitated, panicked, or threatening to hurt themselves. Emergency rooms are also where people go at the end of the month when their medications run out, when their primary care physician can't see them for two weeks, when they are frightened or desperate and have nowhere to turn after 5 pm and their therapist's answering machine tells them to go to the emergency room. Moreover, many of these patients are admitted to and stay in general medical surgical beds for days without proper treatment because of backlogs in psychiatric facilities, creating potentially volatile situations for these patients, staff and other patients.

The number of psychiatric beds in South Carolina has been reduced over the past several years as the Department of Mental Health has closed psychiatric beds in addition to several community hospitals having closed psychiatric beds. According to the Draft Plan, the Department of Mental Health had 3,720 licensed psychiatric beds in 1988 and currently only has 717 licensed psychiatric beds. This is a loss of approximately 3,000 psychiatric beds. In the meantime, the population in South Carolina has grown from approximately 3.2 million people in 1988 to approximately 4.4 million people in 2008. As a result, there is over a million person increase at the same time as an overall decrease in psychiatric beds at both the Department of Mental Health and in general hospitals.

The Draft Plan does indicate a small need for additional psychiatric beds; however, the projected need in some areas does not result in a bed number that is of sufficient size for the development of an economically feasible facility. The Draft Plan uses a planning factor of 70% to project the need for additional beds. Psychiatric units range in size from 8 to 104 beds and this factor does not allow for enough flexibility. General hospital beds are projected using a planning factor of 65% for 0-174 beds. If general hospital beds are planned for at a smaller occupancy factor, then small numbers of psychiatric beds should be planned for at an even smaller number, such as 60%. If a facility only has 20 beds, 60% is 12 beds and 70% is only 14 beds. It only takes a few patients to change the occupancy of a facility with a small number of beds. Consideration should be given to allowing more flexibility in these facilities. The overall occupancy rate in psychiatric units is only 61.7% statewide and the average bed size was 40.5 beds. This is a relatively high occupancy rate for facilities/units with a small number of beds.

By using 75% of the statewide use rate, this has increased the number of beds needed; however, these are still small numbers and may not allow for a sufficient size bed number to constitute an economical unit. The Certificate of Need review staff should also have the flexibility to allow for enough beds to make an economical unit, which in some cases may exist as a free-standing facility, consistent with Federal guidelines for certification of such programs. If a need is indicated for just one additional bed, general hospitals can apply for up to thirty (30) beds to make an economical unit. This same standard should apply to psychiatric beds. For example, if a need is indicated for 20 beds, a facility should be able to apply for up to 30 beds to ensure that there are enough beds/patients to justify the hiring of enough counselors and other staff for this specialized service. This could help alleviate the problems occurring in general hospitals and emergency departments and ensure that the necessary care is provided to this population.

We would suggest that a paragraph be added to this section of the Plan similar to that contained in the general hospital beds need section as follows:

A psychiatric unit should contain a minimum of 30 beds in order to be more economically feasible. An existing unit of less than 30 beds would be allowed to add additional beds in order to increase the size of the unit to 30 beds in order to take advantage of the economies of scale of these specialized units. If the number of beds needed is less than 30, then up to a total of 30 beds could be approved. The applicant must document the need for additional beds based on the economics of construction, historical and projected utilization, floor plan layouts, projected population growth and any other factors that could justify this increased need. Because these facilities will only serve a limited population group, it is necessary to allow for enough beds to make an economical unit.

COMMENTS ON THE REHABILITATION BED NEED SECTION OF THE DRAFT 2008-2009 SOUTH CAROLINA HEALTH PLAN

Pages II-103-105 of the Draft Plan outline the needs for Rehabilitation Facilities throughout South Carolina. The average occupancy rate for these facilities was 73.2% in 2006 which is exceptionally high considering that the average bed size was 40.7 beds. The methodology reflected in the Draft Plan is a considerable improvement over what was formerly used in previous State Health Plans. By using

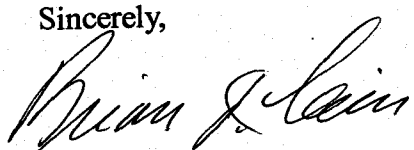
75% of the statewide beds, this has increased the number of beds needed; however, these are still small numbers and may not allow for enough beds to make an economical unit. The Certificate of Need review staff should also have the flexibility to allow for enough beds to make an economical unit, which in some cases may exist as a free-standing facility, consistent with Federal guidelines for certification of such programs. If a need is indicated for just one additional bed, general hospitals can apply for up to thirty (30) beds to make an economical unit. This same concept should apply to rehabilitation beds. For example, if a need is indicated for 20 beds, a facility should be able to apply for up to 30 beds to ensure that there are enough beds/patients to justify the hiring of enough therapists and other staff for this specialized service.

We would suggest that a paragraph be added to this section of the Plan as follows:

A rehabilitation unit should contain a minimum of 30 beds in order to be more economically feasible. An existing unit of less than 30 beds would be allowed to add additional beds in order to increase the size of the unit to 30 beds in order to take advantage of the economies of scale of these specialized units. The facility will justify the need for the additional beds considering the population growth, historical and projected utilization, floor plan layouts and other factors that could justify this increased need. Because these facilities will only serve a limited population group, it is necessary to allow for enough beds to make an economical unit.

Thank you for considering these comments. Because a Plan is only required to be developed every two years, we sincerely hope that the Planning Committee will incorporate these ideas into the final version of the 2008-2009 South Carolina Health Plan. This will enable needed services to be developed in a more expedient manner.

Sincerely,



Brian J. Cain
Managing Partner

#12
J. Thornton Kirby – South Carolina Hospital Association

SCHA South Carolina Hospital Association
1000 Center Point Road | Columbia, SC 29210-5802 | Ph. 803.796.3080 | www.scha.org

February 28, 2008

FEB 29 2008

Mr. Les Shelton
Senior Planner, Division of Planning and Certificate of Need
Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

Dear Les:

Thank you for this opportunity to comment on the Draft 2008 -2009 South Carolina State Health Plan. The hospital community in South Carolina is focused intently on the health care needs of our citizens, and we are hard at work with nearly two dozen partner organizations dedicated to improving the quality and safety of patient care. In addition, we have partnered with physicians, business leaders, and insurers to tackle the problems faced by 700,000 uninsured South Carolinians through the Covering Carolina Collaborative.

Your work to develop a new state health plan is equally critical to the well-being of our citizenry. The South Carolina Hospital Association (SCHA) has encouraged our members to be actively involved in the planning process and to submit their own community-specific comments about the Draft Plan directly to you. In addition, I would like to offer the following comments on issues of importance to the overall membership of SCHA.

General Comments:

First, specific standards for Certificate of Need for Magnetic Resonance Imaging (MRI), which were in the 2004-2005 State Health Plan, are not in the 2008-2009 Draft Plan. SCHA believes each hospital should have at least one MRI unit available for diagnosis of emergency patients, inpatients, and outpatients, and we are offering our recommendations for specific standards later in this letter. However, even with specific standards in previous plans, it often appeared hospitals were really the only applicants who needed to have a CON to offer this service.

For the State Health Plan and the CON process to achieve its goals, all providers must be treated the same. With technology changing so rapidly, DHEC must review all projects using the same standards for all providers – hospitals, physicians or private entities. SCHA would welcome the opportunity to work with the Department and the Planning Committee to develop improvements to the review process to insure consistency of review.

Second, the Draft 2006-2007 State Health Plan which was approved for public comment, but never adopted, contained a section with specific minimum criteria for the construction of new hospitals. Unfortunately, that standard and the minimum criteria are not in the current Draft Plan. Other states, including North Carolina in their 2008 State Medical Facilities Plan, have recognized the need for this type of criteria. Therefore, SCHA requests that the DHEC staff and the State Health Planning Committee review the varied roles hospitals must play in their local communities and establish minimum criteria for the establishment of any new general hospital. Our specific recommendations for those criteria are contained herein.

Highlighting this need, a recent report by the Department of Health and Human Services' Office of the Inspectors General (OIG), found physician-owned specialty or limited service hospitals are poorly equipped to handle emergency care. This OIG report stated that only about half of the limited service specialty hospitals had emergency departments, and most of those had only one bed. Additionally, this report stated that some of these specialty hospitals did not always have nurses on duty and physicians on call or on duty as required by Medicare. Two thirds of these hospitals had instructed their staff to call 9-1-1 as part of their emergency response procedures. The OIG recommended that The Centers for Medicare and Medicaid Services (CMS) develop a system to identify and track limited-service hospitals to ensure that these hospitals meet Medicare staffing requirements and can provide initial treatment of emergencies without relying on a 9-1-1 response to transfer the patients to a full-service hospital. The CMS has agreed to this recommendation.

Third, the population of a county without a hospital, unless combined into a service area, is never factored into the bed projection of a hospital(s) or a county. Even though these counties without hospitals are generally smaller in terms of population, they could still impact both hospitals in the immediate area and regional referral centers. Therefore, SCHA recommends that DHEC staff should review the issue of counties without a hospital and propose some methodologies for calculating and accounting for their impact in future plans.

Specific Comments:

Chapter II, Section: General Hospital Beds:

This overall section is titled "General Hospitals" and the narrative section titled "General Hospital Beds" outlines the general acute hospital bed need methodology. It uses the actual demand or utilization data for the general acute hospitals of the state. The needs for more specialized services such as rehabilitation or psychiatric services are contained in other sections of the Draft Plan. Therefore, any new hospital which is proposed as a result of the need projected in this section should be a general acute hospital, meeting the same requirements of other general acute hospitals inventoried in this section.

Therefore, SCHA recommends the following new criteria:

No additional hospitals will be approved unless they are a general hospital and will provide:

(1) A 24-hour emergency services department, and meets the requirements to be a Level III emergency service as defined in Regulation 61-16 Sec. 613 Emergency Services

(2) Inpatient medical services to both surgical and non-surgical patients, and

(3) Medical and surgical services on a daily basis within at least six of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services (CMS), as follows:

MDC 1: Diseases and disorders of the nervous system
MDC 2: Diseases and disorders of the eye
MDC 3: Diseases and disorders of the ear, nose, mouth and throat
MDC 4: Diseases and disorders of the respiratory system
MDC 5: Diseases and disorders of the circulatory system
MDC 6: Diseases and disorders of the digestive system
MDC 7: Diseases and disorders of the hepatobiliary system and pancreas
MDC 8: Diseases and disorders of the musculoskeletal system and connective tissue
MDC 9: Diseases and disorders of the skin, subcutaneous tissue and breast
MDC 10: Endocrine, nutritional and metabolic diseases and disorders
MDC 11: Diseases and disorders of the kidney and urinary tract
MDC 12: Diseases and disorders of the male reproductive system
MDC 13: Diseases and disorders of the female reproductive system
MDC 14: Pregnancy, childbirth and the puerperium

MDC 15: Newborns/other neonates with conditions originating in the perinatal period
MDC 16: Diseases and disorders of the blood and blood-forming organs and immunological disorders
MDC 17: Myeloproliferative diseases and disorders and poorly differentiated neoplasms
MDC 18: Infectious and parasitic diseases
MDC 19: Mental diseases and disorders
MDC 20: Alcohol/drug use and alcohol/drug-induced organic mental disorders
MDC 21: Injury, poisoning and toxic effects of drugs
MDC 22: Burns
MDC 23: Factors influencing health status and other contact with health services
MDC 24: Multiple significant traumas
MDC 25: Human immunodeficiency virus infections

Any applicant for a new hospital must provide a written commitment that the facility will accept Medicare and Medicaid patients, and that unreimbursed services for indigent and charity patients are provided at a percentage which meets or exceeds other hospitals in the service area.

Concerning the specific bed need methodology, we recommend that Standard 4 (d) on page II-7 be revised to read:

If a county indicates a surplus of beds, then no additional beds will be approved unless an individual hospital in the county indicates a need for additional beds. Should an individual hospital indicate a need for additional beds, then a maximum of the actual projected bed need or up to 30 additional beds may be approved for that hospital to allow for the construction of an economical unit at the existing hospital site as part of an expansion or renovation project. If the existing hospital is relocating or has relocated in whole or part to another site, then a maximum of the actual projected bed need or up to 50 additional beds may be approved for that hospital to allow for the construction of an economical satellite hospital at that site. The hospital requesting the addition must document the need for additional beds beyond those indicated as needed by the methodology stated above, based on historical and projected utilization, as well as projected population growth or other factors demonstrating the need for the proposed beds. Additional beds will only be approved for the specific hospital indicating a need.

Chapter II, Long-Term Care Hospitals, pages II-21 to II-23:

We recommend that Standard (4) on page II-22 be revised to read:

A Certificate of Need is required to convert LTCH beds to general acute care beds, rehab beds, or psych beds.

Additionally, we recommend two new standards:

Create a new standard: A hospital which desires to be designated as an LTAC and has been awarded a CON for that purpose, must be certified as an LTAC by CMS within 24 months of accepting its first patient, or the CON issued to that hospital for that purpose shall be revoked. That entity which has had its CON revoked shall not have the authority to operate as a general acute care hospital.

Create a new standard: An acute care hospital which has been awarded a CON to convert acute care beds for use in creating an LTAC, may again use its beds for acute care regardless of bed need within the county. If it is unable to acquire CMS certification as an LTAC, or if it no longer wishes to operate as an LTAC at that time, the hospital beds will revert to the official inventory of beds within that hospital.

Chapter II, Megavoltage Radiotherapy and Radiosurgery, pages II-59 to II-68:

1. The planning capacity of a standard linear accelerator is very different than the average treatment time for more specialized techniques such as total body irradiation and specialized modalities such as a Cyberknife. Therefore, SCHA recommends that the Radiotherapy section be segmented to reflect the need for standard services and the need for the more specialized techniques and modalities.

2. SCHA recommends that the planning capacity for a Cyberknife should be reduced to 900 annual treatments. The planning capacity of 4,000 annual treatments contained in the Draft is not a realistic capacity according to specifications of vendors.

3. Revise Standard (4) B on page II-62 pertaining to a new provider's application for equipment to read:
An applicant must project that the proposed service will perform a minimum number of treatments equal to 50 percent of capacity annually within three years of initiation of services, without reducing the utilization of the existing machines in the service area below the 80 percent threshold. The applicant must document where the potential patients for this new service will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. Letters of support from referring physicians, with expected annual referral volumes, must be included.

4. Revise Standard (5) on page II-62 pertaining to an existing providers' application for equipment to read: Expansion of an existing service shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for the past two years and can project a minimum use rate of 50 percent of capacity per year on the additional equipment within three years of its implementation.

If the additional equipment is a specialized radiotherapy unit as described in Standard 2, then the existing provider may propose an annual capacity for that additional equipment, based on the specialized use of the equipment by that applicant. If this proposed annual capacity can be justified by the applicant, then this capacity will be used in CON application calculations, as well as future capacity calculations, for that applicant.

5. DHEC should include the MRI Standards from the 2004-2005 Plan in the 2008-2009 Plan. Those standards are:

1. Each hospital should have at least one MRI unit available for diagnosis of emergency patients, inpatients, and outpatients.

2. In order to promote cost-effectiveness, the use of shard mobile MRI units should be considered.

3. The applicant agrees in writing to provide to the Department utilization data on the operation of the MRI service.

Chapter II, Ambulatory Surgical Facility, pages II-72 to II-80:

1. SCHA recommends that Standard (#3) on page II-73 be revised to read: For a new facility, the applicant must document where the potential patients for the facility will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. That documentation and projections of shifts must be shared with existing providers of surgical services in the county, and the applicant must provide documentation that has occurred. For an existing facility seeking expansion, the applicant must provide patient origin information on the current facility.

2. We recommend that Standard (#6) on page II-73 be revised to read: "The applicant must document the potential impact that the proposed new ASF or expansion will have upon existing service providers and referral patterns. To validate the projected impact, DHEC will survey all existing hospitals and free standing ASFs in the county concerning existing capacity and need. The results of these surveys will be a factor in evaluating possible adverse effects of duplication of service."

3. We recommend the creation of a new standard: Because of the substantial growth of ASFs and the concern that ASFs are being proposed as a method of increasing reimbursement for procedures currently being performed in physician offices, preference will be given to new hospital owned ASFs, or those joint-ventured with hospitals.

Chapter II, Emergency Hospital Services, pages II-81 to II-82:

1. While SCHA agrees with Standard (2) on page II-81 that all off-campus emergency services must be an extension of an existing hospital's emergency service, we recommend that it be revised to read: All off-campus emergency services must be an extension of an existing hospital's emergency service in the same county. The hospital must have a license that is in good standing and must be in operation to support the off-campus emergency services.

2. Create a new standard: The proposed freestanding emergency service must be located no closer than 30 minutes travel time from an existing hospital emergency department or off-campus emergency service. SCHA believes travel time is a more appropriate measure than mileage.

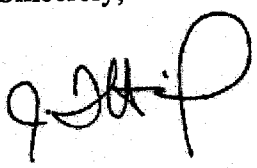
3. Create a new standard: The applicant must demonstrate need for this service by documenting where the potential patients for this proposed service will come from and why they are not being adequately served by existing services in the area.

Local Inpatient Crisis Stabilization Beds, pages II-84 to II-86:

Given the continuing problem with mental health patients being held in hospital emergency departments for inordinate periods of time waiting for an appropriate inpatient psychiatric bed to become available, SCHA commends DHEC and SC DMH for crafting a provision for Local Inpatient Crisis Stabilization Beds. However, this provision must not be used as a tactive to avoid CON review for acquiring psychiatric beds. Both DHEC and SC DMH must create an inventory of these beds and the number of patients being served in these beds to ensure that providers are using the beds to address the need for which this provision was created.

Thank you for consideration of our comments. Please do not hesitate to contact me if I can answer any questions or provide any clarification. We always appreciate the opportunity to work with you and your staff.

Sincerely,

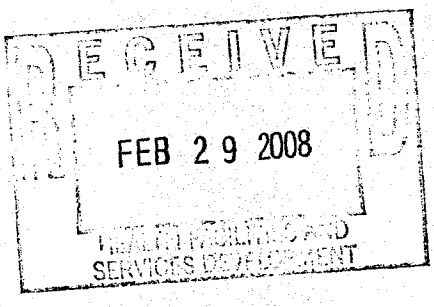


J. Thornton Kirby
President and CEO

#13
Sister Judith Ann Karam – Providence Hospital

SISTERS OF CHARITY
PROVIDENCE HOSPITALS

February 29, 2008



Mr. Les Shelton
Division of Planning and Certificate of Need
South Carolina Department of Health
and Environmental Control
The South Carolina Health Planning Committee
1777 St. Julian Place, Suite 201
Columbia, SC 29204

RE: Draft 2008-2009 South Carolina Health Plan

Dear Mr. Shelton and Committee Members:

Thank you for providing Sisters of Charity Providence Hospitals ("Providence Hospitals") the opportunity to comment on the *"Draft 2008-2009 South Carolina Health Plan."* Providence Hospitals supports the state health planning process as means of identifying unmet needs for health services in our state. To this end we offer the following comments:

Certificate of Need Standards for Cardiac Catheterization:

Providence Hospitals is concerned about attempts to amend the South Carolina Health Plan to allow hospitals to provide therapeutic cardiac catheterization without open heart surgery by participation in the Atlantic C-PORT II Trial. The American College of Cardiology and the American Heart Association have stated that elective/non-primary percutaneous coronary intervention (PCI) or coronary angioplasty should not be performed without open heart surgical back up.

Providence Hospitals is supportive of the current standards for the provision of emergency PCI in hospitals without an on-site comprehensive cardiac catheterization laboratory and an open heart surgery program. These standards provide South Carolina hospitals the ability to save the lives of patients suffering from a heart attack. Elective PCI, however, can be performed hours or even days after a diagnosis is made and elective PCI is rarely, if ever, scheduled for a patient who is actually suffering from an acute heart attack. It would be unprecedented, since the inception of the South Carolina Health Planning process, for the Health Planning Committee to support a "clinical trial," like the proposed C-PORT trial, that is directly in contravention of the position supported by the mainstream medical community like the American College of Cardiology and American Heart Association. Patient safety is too important to compromise just for the purpose of promoting a clinical study, particularly in a state where access to cardiac care is not an issue.

The only hospital that publicly spoke in favor the C-PORT study at the public hearings requested that certain standards be eliminated. These standards limited hospital participation to those that are not within a thirty minute drive time of existing providers and required participating hospitals also apply for a CON for emergency angioplasty. It makes little clinical sense to seek the ability to provide elective PCI without also offering life-saving emergency PCI. In addition, if a provider is within a thirty minute drive time of an existing provider, there is clearly no access issue. Further, this hospital offered no clinical support from its cardiologists in support of its position.

Open Heart Surgery:

Background

Since 2000, the number of open heart surgeries has continued to decline. This event has occurred not only in South Carolina but throughout the United States. The cause of the decline in open heart surgery is a result of new technology allowing the placement of stents to open clogged arteries in the heart. We are now treating patients with a different technology. The number of patients who have had stent placement has risen dramatically over the past five years.

The state of South Carolina has 17 open heart programs that are geographically spread equally through out the state to assure appropriate access to all of the citizens of South Carolina. These existing open heart surgery providers are within sixty (60) minutes travel time of the majority of residents of South Carolina. Despite rising populations, South Carolina's open heart surgery programs have seen their volumes continually decline since 2000. Statewide, open heart surgery volumes decreased from 5,893 in 2005 to 5,483 in 2006. this represents over 7% decline in overall open heart survivor volumes. Providence Hospital's volume decreased from 939 procedures in 2005 to 826 in 2006. This represents a 12% decline.

There is also significant unused open heart surgery capacity in the state. According to the Draft 2008-2009 Plan, the statewide average utilization rate is 31.1%. This equates to 155.4 open heart procedures per suite. This is well below the 200 procedures per unit noted as the minimum volume in the Plan. Furthermore, as the Plan notes, studies indicate that hospitals that perform a minimum of 350 procedures annually, tend to have better outcomes than those that perform fewer procedures. In 2006, only 7 open heart surgery programs met this quality threshold.

Providence Hospitals is in support of the current proposed language in the draft 2008-2009 South Carolina Health Plan. We understand that Lexington Medical Center ("LMC") intends to propose an amendment to the Draft 2008-2009 South Carolina Health Plan that would provide a special exception that applies to LMC only, as part of its strategy to develop a third open heart surgery program in the Midlands. Such an exception would be totally inconsistent with the excess open heart surgery capacity in the Midlands and statewide, inconsistent with the declining trend in the number of open heart surgeries, inconsistent with the applicable CON statutes and regulations, particularly in the area of unnecessary duplication and adverse impact, and certainly not in the best interest of quality patient care. In addition to causing a further decline in the

volumes of existing providers, the addition of new open heart programs would dilute the limited personnel resources which also affects quality and increases health care cost.

LMC's CON application to develop an open heart surgery program was denied by DHEC's Division of Certification of Need. After an exhaustive trial lasting over a month, an administrative law judge rejected LMC's appeal. The governor vetoed a legislative attempt to allow LMC to bypass the state health planning process. The legislature upheld that veto. LMC has failed at every level to demonstrate a need for a third open heart program in the Midlands.

A copy of the order from the Administrative Law Judge referred to above is attached. Also attached is a copy of a Power Point presentation analyzing LMC's prior amendment to the 2007 Draft Plan for open heart surgery and the C-Port trial.

Further, Providence supports the proposed change provided for in the draft Plan on page II-53 that increases the ratio to (7) diagnostic cardiac catheterizations performed generating (1) open heart surgery. The (4) to (1) ratio currently used is outdated and is not supported by current data.

Again, thank you for your consideration of our comments and recommended changes. They are offered in spirit of improving care and access to quality services for the citizens of South Carolina.

Sincerely,

Sr. Judith Ann Karam, CSA

Sister Judith Ann Karam, CSA
CEO, Sisters of Charity Providence Hospitals

Enclosures (2)

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

Lexington County Health Services District, Inc., d/b/a Lexington Medical Center, Petitioner, vs. South Carolina Department of Health and Environmental Control; Sisters of Charity Providence Hospital; and Palmetto Health Alliance, Palmetto Health Richland, Respondents.	)	**FINAL ORDER AND DECISION** **DOCKET NO. 04-ALJ-07-0365-CC**

APPEARANCES:

David B. Summer, Jr., Esquire
Faye A. Flowers, Esquire
For Petitioner Lexington Medical Center

Nancy S. Layman, Esquire
Ashley C. Biggers, Esquire
For Respondent South Carolina Department of Health and Environmental Control

James G. Long, III, Esquire
Philip Wesley Jackson, II, Esquire
For Respondent Providence Hospital

M. Elizabeth Crum, Esquire
Ariail B. Kirk, Esquire
Pamela A. Baker, Esquire
For Respondent Palmetto Health Richland

STATEMENT OF THE CASE

The above-captioned matter comes before this Court upon the request of Petitioner Lexington County Health Services District, Inc., d/b/a Lexington Medical Center ("LMC"), for a contested case hearing to challenge the decision of Respondent South Carolina Department of Health and Environmental Control ("DHEC" or "Department") to deny its application for a Certificate of Need

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SC ADMIN. LAW COURT

(CON) for the development of an open-heart surgery program and therapeutic cardiac catheterization program at its hospital in West Columbia, South Carolina. The Department denied LMC's CON application based upon its finding that the implementation of LMC's proposed cardiac program would result in an unnecessary duplication of such services in the Midlands and would have an undue adverse impact upon existing providers of cardiac services in the area. Two of those existing providers, Respondents Sisters of Charity Providence Hospital ("Providence") and Palmetto Health Alliance, Palmetto Health Richland ("Palmetto"), intervened in this matter in support of the Department's decision to deny LMC's CON application.

Prior to a hearing on the merits of this matter, the parties conducted extensive discovery, generating some 30,000 pages of documents and deposing over 40 individuals, and this Court heard a number of motions on discovery issues and other preliminary matters. After timely notice to the parties, a contested case hearing on the merits of this case was held from February 13, 2006, through March 10, 2006, for a total of sixteen days of trial. During the hearing, all four parties presented witnesses and offered exhibits in support of their respective positions. A total of twenty-two witnesses testified at the hearing, and the Court admitted seventy-seven exhibits into evidence, in addition to receiving two proffers of evidence. The following witnesses were designated as experts in the following areas of specialization: Dr. James Morris and Dr. Reid Tribble in the area of Cardiovascular and Open-Heart Surgery; Dr. Edward Leppard in the area of Cardiovascular Surgery; Dr. Leon Khoury, Dr. Stan Juk, Dr. Barry Feldman, and Dr. Myron Bell in the field of Cardiology; Dr. Richard Boyer in the area of Emergency Medicine; Richard Baehr and David Levitt in the field of Healthcare Planning and Finance; Martin Brown in the area of Healthcare Finance; and Joel Grice in the field of Healthcare Planning.

Having reviewed all of the documentary and testimonial evidence presented at the hearing, having considered the arguments of the parties made at the hearing and in their post-trial filings, and having followed the applicable law, I find that DHEC properly denied LMC's CON application for an open-heart surgery program at its West Columbia hospital because the implementation of the proposed program would conflict with the policies regarding the establishment of such programs set forth in the 2003 State Health Plan, would constitute an unnecessary duplication of cardiac services

in the Midlands, and would have a materially adverse impact upon existing open-heart surgery providers in the market.

FINDINGS OF FACT

Having carefully considered all testimony, exhibits, and arguments presented at the hearing of this matter, and taking into account the credibility and accuracy of the evidence, I make the following Findings of Fact by a preponderance of the evidence:

I. The Parties

1. Petitioner LMC is a not-for-profit, governmental incorporated health services district that operates a vertically integrated health care system primarily serving the citizens of Lexington County, South Carolina. This system consists of a 346-bed acute care hospital located in West Columbia, South Carolina, a 388-bed nursing home and Alzheimer center, 6 community medical centers providing urgent care services throughout Lexington County, and a network of 36 physician practices employing approximately 115 primary care and specialty physicians. In its CON application, LMC proposes to provide open-heart surgery and therapeutic cardiac catheterization services at its main hospital campus in West Columbia, which is located near the intersection of Interstate 26 and Highway 378.

2. Respondent South Carolina Department of Health and Environmental Control is a state agency charged with, among other things, implementing South Carolina's Certificate of Need regulatory program, which includes licensing standards for the provision of open-heart surgery services and certain other cardiac care services.

3. Respondent Providence Hospital is a private charitable hospital that operates two hospital facilities in Columbia, including its main hospital and heart institute located on Forest Drive in downtown Columbia. Providence has provided open-heart surgery services since 1974 and is the second oldest open-heart surgery provider in South Carolina.

4. Respondent Palmetto Health Richland is a non-profit 579-bed general acute care hospital located in downtown Columbia near the intersection of Sunset Drive and South Carolina Route 277. Palmetto is the major teaching hospital in the Midlands and operates the area's only Level 1 trauma center. Palmetto has provided open-heart surgery services for twenty-five years and

has recently opened a "heart hospital" specifically dedicated to providing cardiac services.

II. Regulatory Background

A. Generally

5. This matter arises under South Carolina's comprehensive Certificate of Need (CON) regulatory program for health care facilities and services, which consists of the State Certification of Need and Health Facility Licensure Act found at S.C. Code Ann. §§ 44-7-110 to 44-7-370 (2002 & Supp. 2005), the accompanying CON regulations found at 24A S.C. Code Ann. Regs. 61-15 (Supp. 2005), and a State Health Plan which is revised at least biennially. The purpose of this regulatory scheme is to "promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State." See S.C. Code Ann. § 44-7-120 (2002).

6. The primary vehicle by which this regulatory program is implemented and its stated goals achieved is the requirement that a health care facility apply for, and receive, a CON from DHEC prior to undertaking certain major projects or providing certain new services. See S.C. Code Ann. §§ 44-7-120, 44-7-160 (2002). In determining whether to grant or deny an application for a CON, the Department evaluates the proposed project under the review criteria found in the CON regulations and under the policies and standards set out in the State Health Plan. See S.C. Code Ann. § 44-7-210(C) (2002). The project review criteria set forth in Regulation 61-15 include thirty-three separate criteria that fall into five general categories: (1) criteria related to the need for the proposed project, (2) criteria related to the economic considerations of the project, (3) criteria related to the project's impact on the resources of the health care system, (4) criteria related to the suitability of the site of the project, and (5) criteria related to certain special considerations, such as the project's ability to serve medically underserved groups. See 24A S.C. Code Ann. Regs. 61-15, §§ 801, 802. As required by the CON Act, the State Health Plan contains the following statistics, standards, and findings with regard to the various facilities and services regulated by the CON Act:

> (1) an inventory of existing health care facilities, beds, specified health services, and equipment;
> (2) projections of need for additional health care facilities, beds, health services, and

> equipment;
> (3) standards for distribution of health care facilities, beds, specified health services, and equipment including scope of services to be provided, utilization, and occupancy rates, travel time, regionalization, other factors relating to proper placement of services, and proper planning of health care facilities; and
> (4) a general statement as to the project review criteria considered most important in evaluating certificate of need applications for each type of facility, service, and equipment, including a finding as to whether the benefits of improved accessibility to each such type of facility, service, and equipment may outweigh the adverse affects caused by the duplication of any existing facility, service, or equipment.

S.C. Code Ann. § 44-7-180(B) (2002).

7. The 2003 State Health Plan was in effect at the time LMC filed its application for a CON to establish open-heart surgical services and therapeutic cardiac catheterization services and, therefore, the standards, findings, and policies set forth in the 2003 Plan are applicable to the review of LMC's CON application. See 24A S.C. Code Ann. Regs. 61-15, § 504. With regard to cardiovascular services, the 2003 State Health Plan sets forth separate definitions, standards, and review criteria for CONs for open-heart surgery and for cardiac catheterizations.

B. Standards and Definitions

8. Under the Plan, open-heart surgery is defined as "an operation performed on the heart or intrathoracic great vessels." See DHEC Ex. #2, at II-46. The most common open-heart surgery is coronary artery bypass grafting, or CABG, which is a highly invasive operation that entails harvesting a blood vessel from another area of the body and using it to bypass a blocked section of the coronary artery. These procedures are often done with the temporary use of a heart-lung bypass machine, although surgeons are increasingly performing CABGs while the patient's heart is still beating. Other open-heart surgeries include operations to repair congenital heart defects and surgeries to repair defects in the heart valves.

9. The Plan sets the capacity of an open-heart surgery program at 500 open-heart procedures per year for each open-heart operating room, and defines the service area for open-heart surgery services as the area within a 60-minute one-way automobile drive of the facility. See DHEC Ex. #2, at II-48. The Plan further emphasizes that an open-heart surgery program should perform a minimum of 200 open-heart surgeries per unit each year to maintain its proficiency, and that

improved results in the quality of care are found when a program performs at least 350 open-heart surgeries per unit annually. See DHEC Ex. #2, at II-35, II-36.

10. A cardiac catheterization is an invasive medical procedure performed within a cardiac catheterization laboratory, also known as a "cath lab," during which a thin, flexible catheter is inserted into a blood vessel as a diagnostic or therapeutic tool for heart and circulatory conditions. See DHEC Ex. #2, at II-37. Diagnostic catheterizations involve the use of a catheter to inject dye in the blood vessel to determine the amount of blockage in an artery; the most common therapeutic catheterizations, also known as angioplasties, involve the use of an inflatable balloon to unblock a clogged artery, often with the insertion of a stent into the artery to keep the artery open. That is, as their names imply, diagnostic catheterizations simply diagnose the extent of blockage in an artery, while therapeutic catheterizations actually treat the blockage itself.

11. The 2003 State Health Plan sets out different standards for CON approval of diagnostic cath labs and "comprehensive" cath labs that perform both diagnostic and therapeutic catheterizations. See DHEC Ex. #2, at II-38 to II-41. For example, the service area for a diagnostic cath lab is the area within a 45-minute one-way automobile drive of the lab, while the service area for a comprehensive cath lab reaches to a 60-minute one-way drive from the lab. Further, given the risks associated with therapeutic cardiac catheterization, comprehensive cath labs may only be located in hospitals that provide open-heart surgery services, whereas diagnostic cath labs may be located in facilities that do not offer open-heart surgery services. The capacity of a cath lab is also weighted according to the type of catheterization performed; specifically, under the 2003 State Health Plan, the capacity of a cath lab is defined to be 1,200 procedures annually, with diagnostic catheterizations each counting as one procedure and therapeutic catheterizations each counting as two procedures toward the total.

III. Application Process

12. On April 21, 2004, Petitioner LMC submitted an application to the Department for a CON for the development of a comprehensive cardiac program at its West Columbia hospital, to include both open-heart surgical capabilities and therapeutic cardiac catheterization capabilities. Specifically, LMC proposed the addition of two dedicated open-heart surgery suites—one of which

would be designated as a "back-up" surgery suite—and a second cardiac catheterization laboratory to complement its existing diagnostic catheterization laboratory. As part of the project, LMC would also develop additional services to support the proposed open-heart surgery program, including the creation of a separate, dedicated intensive care unit for cardiac patients. If approved, the proposed project would authorize LMC to perform open-heart surgery and provide comprehensive cardiac catheterization services.

13. By a letter dated May 21, 2004, the Department deemed LMC's CON application to be complete and set forth the most relevant project review criteria for the evaluation of LMC's application. These criteria, ranked in order of their importance, were as follows:

1. Compliance with the Need as outlined in the 2003 South Carolina Health Plan-1

2. Community Need Documentation-2a, 2b, 2c, 2e
Distribution (Accessibility)-3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h
Adverse Effects on Other Facilities-23a, 23b

3. Projected Revenues-6a, 6b, 6c
Projected Expenses-7
Financial Feasibility-15
Cost Containment-16c

4. Staff Resources-20a, 20b

5. Acceptability-4a, 4b

DHEC Ex. #1, at 524.

14. On August 10, 2004, the Department held a project review meeting concerning LMC's CON application. At the meeting, presentations were made by LMC in support of the project and by Providence and Palmetto in opposition to the proposed project.

15. Based upon LMC's CON application and the information collected during the project review process, the Department issued a decision denying LMC's application on October 22, 2004. In the decision, the Department concluded that, while LMC's project met the technical standards for adult open-heart surgical services set forth in the 2003 State Health Plan, the project was ultimately inconsistent with Sections 802(3)(a), 802(3)(b), and 802(23)(a) of Regulation 61-15, which address

the unnecessary duplication of health care services and the adverse impact of proposed services upon existing providers. In particular, the Department found that

> this proposal would unnecessarily duplicate existing open-heart surgical services performed at Palmetto Health Richland Memorial Hospital and Providence Hospital because their services are geographically accessible to Lexington Medical Center's target population. Such duplication of services is not justifiable due to the reduction in the growth of open-heart surgical services that is occurring at this time. As a result, the proposed project would have an adverse impact on the current and projected use rates of these existing open-heart surgery providers. In addition, as documented in the 2003 State Health Plan, the State Health Planning Committee, recognizing the important correlation between volume and proficiency, further acknowledges that the number of open-heart surgery cases is decreasing and that maintaining volume in programs is very important to the provision of quality care to the community.

DHEC Ex. #1, at 846.

16. Petitioner LMC timely requested a contested case hearing before this Court to challenge the Department's denial of its CON application. Respondents Providence and Palmetto were subsequently granted leave to intervene in this matter in opposition to Petitioner's CON application.

IV. Availability and Use of Open-Heart Surgery Services in the Midlands

A. Generally

17. There are three existing open-heart surgery programs within LMC's service area—that is, within a 60-minute one-way drive of LMC. These programs are located at Providence Hospital and Palmetto Health Richland Hospital in downtown Columbia and Aiken Regional Medical Center in Aiken, South Carolina. While there are three open-heart surgery providers within LMC's service area, there are no open-heart surgery programs located within the boundaries of Lexington County.

18. Providence Hospital currently has four open-heart surgery suites. With a stated capacity of 500 open-heart procedures per year for each operating room, Providence has a total annual capacity of 2,000 open-heart surgeries at the hospital. In fiscal year 2005, Providence performed 939 open-heart surgeries, leaving the hospital with an excess capacity of 1,061 heart surgeries, or over 50% excess capacity, for the year.

19. Palmetto Health Richland Hospital has two open-heart surgery units, for an annual capacity of 1,000 open-heart procedures at the hospital. In fiscal year 2005, Palmetto performed 410 open-heart surgeries at its hospital. Therefore, for 2005, Palmetto had an excess capacity of 590 open-heart surgeries, or 59% excess capacity.

20. Aiken Regional Medical Center is likewise well below its capacity for open-heart surgeries. With one open-heart surgical suite, Aiken Regional Medical Center has the capacity to perform 500 open-heart surgeries per year. However, in fiscal year 2004, Aiken only performed 107 open-heart surgical procedures, leaving the hospital with an excess capacity of 383 surgeries, or 78% excess capacity. In fact, this excess capacity for open-heart surgeries exists statewide, with few, if any, of South Carolina's open-heart surgery providers utilizing more than 50% of their capacity to perform open-heart surgeries in recent years.

21. Much of this excess capacity is the result of a state and national trend away from open-heart surgery toward other treatments for coronary artery disease, including the use of therapeutic catheterization to place stents in blocked vessels. During the 1980s and 1990s, both the number of open-heart surgeries performed and the use rate for such surgeries increased dramatically in South Carolina, leading to a proliferation of open-heart surgery programs in the state. However, with developments in the use of therapeutic catheterization to treat heart problems in the late 1990s and early 2000s, and, in particular, with the development of the drug-eluting stent to open blocked vessels in 2003, the number of open-heart surgeries performed in South Carolina has declined dramatically since the year 2000, reflecting a similar trend throughout the nation.

22. After peaking at 6,473 surgeries in 2000, the number of open-heart surgeries performed in South Carolina has steadily declined, falling to 5,850 surgeries in 2004 despite an increase in the state's population during that time. Accordingly, the use rate for open-heart surgery in South Carolina has also shown a dramatic decline in the past several years, dropping from 164 surgeries per 100,000 residents in 2000 to 139 surgeries per 100,000 residents in 2004.

23. These statewide numbers are reflected in the data for the open-heart surgeries performed at Providence and Palmetto. The volume of open-heart surgeries performed at Providence has declined from a peak of around 1,100 surgeries per year in 1998 and 1999 to the 939 surgeries

performed in 2005, and the number of open-heart surgeries at Palmetto has fallen from a peak of 499 surgeries performed in 2002 to the 410 open-heart procedures performed in 2005 at the hospital.

24. I find that, based upon the evidence presented at the hearing, the use rate for open-heart surgery will continue to decline in South Carolina, such that, even with an increasing population in LMC's service area, the number of open-heart surgery procedures performed in the Midlands in the future will, at best, be stagnant and, in all likelihood, will continue to decline.[1]

B. Lexington County Residents

25. Providence and Palmetto Hospitals are located in downtown Columbia, less than seven miles from LMC's main hospital campus in West Columbia—the location of LMC's proposed open-heart surgery program—and approximately sixteen miles from downtown Lexington. Specifically, LMC is located approximately 6.4 miles from Providence and 6.7 miles from Palmetto.

26. In 2004, residents of Lexington County constituted approximately 20% of Providence's open-heart surgery patients and approximately 29% of Palmetto's open-heart surgery patients. And, the three largest cardiology groups in Richland County have offices in Lexington County and treat patients from Lexington County.

27. In fact, the overall use rate for open-heart surgery is significantly higher for residents of Lexington County than it is for Richland County residents, which would suggest that Lexington County residents have equal, if not greater, access to open-heart surgical services than residents of Richland County.

28. I find that there are no geographic, social, or economic barriers restricting the ability of Lexington County residents to access open-heart surgical services at either Providence or Palmetto.

C. Transfers of Open-Heart Surgery Patients

29. One of the primary concerns raised by LMC with regard to the accessibility of open-heart surgery to Lexington County residents is the time and inconvenience required to transfer

[1] Notably, while there was some disagreement as to the extent of this decline, all of the experts presented at the hearing, including Petitioner's health planning expert, agreed that the use rate for open-heart surgery in LMC's service area, and the state as a whole, would continue to decline in coming years.

patients from LMC to Providence or Richland for open-heart surgery, particularly in emergency situations.

30. However, according to the testimony of the medical experts presented at the hearing, emergency open-heart surgery is very rarely performed, and the vast majority of open-heart surgery procedures are elective procedures performed on stable patients, scheduled at the convenience of the surgeon and the patient.[2] For such scheduled surgeries on stable patients, the short transfer from LMC to Providence or Palmetto does not deny Lexington County residents access to open-heart surgical services.

31. Further, the evidence presented at the hearing suggests that even these transfers of stable patients are fairly rare. As a result of the 1,532 diagnostic catheterizations performed at LMC in 2005, only 189 patients—or approximately 12% of the total number of catheterizations—were transferred from LMC's cath lab to either Providence or Palmetto for open-heart surgery.

32. Therefore, although some patients must be transferred from LMC to Providence or Palmetto for open-heart surgery, this fact alone does not demonstrate a need for an open-heart surgery program at LMC.

V. Availability and Use of Therapeutic Cardiac Catheterizations in the Midlands

A. Generally

33. There are three existing comprehensive cardiac catheterization programs—that is, programs performing both diagnostic and therapeutic catheterizations—within a 60-minute one-way drive of LMC. These programs are located at Providence Hospital and Palmetto Health Richland Hospital in downtown Columbia and Aiken Regional Medical Center in Aiken, South Carolina. Given the risks associated with performing therapeutic cardiac catheterizations, these comprehensive cardiac catheterization laboratories are only authorized for hospitals that are approved for, and provide, open-heart surgical services. LMC currently is approved for, and provides, diagnostic cardiac catheterization services in one cardiac catheterization laboratory at its West Columbia

[2] For example, the standard of care for treating the most common emergent cardiac condition, an ongoing acute myocardial infarction, or heart attack, is to open the blocked artery by performing a therapeutic catheterization, such as an angioplasty, on the patient, rather than performing a complex, open-heart surgery, such as a CABG, on the patient.

hospital.

34. In these programs, Providence Hospital has six cardiac catheterization laboratories, Palmetto Health Richland has three cardiac catheterization laboratories (with a fourth cath lab approved, but not yet constructed), and Aiken Regional Medical Center has one cardiac catheterization laboratory, for a total of ten existing and one forthcoming comprehensive cardiac cath labs in LMC's service area. In 2004, Providence performed 2,749 therapeutic catheterizations in its six cath labs and Palmetto performed 791 therapeutic catheterizations in its three cath labs; in 2003, Aiken Regional Medical Center performed 323 therapeutic catheterizations in its cath lab.

35. With the increased preference for the use of therapeutic catheterization to treat common cardiac conditions, such as coronary artery disease, rather than open-heart surgery, I find that the use rate for therapeutic cardiac catheterizations in the Midlands will likely increase modestly over the next several years, resulting in modest increases in the number of therapeutic catheterizations performed during that time.

B. Lexington County Residents

36. As noted above, the comprehensive cardiac catheterization laboratories at Providence and Palmetto Hospitals are located less than seven miles from LMC's main hospital campus in West Columbia, the location from which it proposes to provide therapeutic cardiac catheterization services.

37. In 2004, residents of Lexington County constituted approximately 23% of Providence's therapeutic cardiac catheterization patients and approximately 31% of Palmetto's therapeutic cardiac catheterization patients. And, the three largest cardiology groups in Richland County have offices in Lexington County and treat patients from Lexington County.

38. The use rate for therapeutic cardiac catheterization services is significantly higher for residents of Lexington County than it is for Richland County residents, which would suggest that Lexington County residents have equal, if not greater, access to therapeutic cardiac catheterization services than residents of Richland County.[3]

[3] In fact, 356 patients were transferred from LMC's diagnostic cath lab to receive therapeutic cardiac catheterization at either Providence or Palmetto in 2005.

39. I find that, based upon the evidence presented at the hearing, there are no geographic, social, or economic barriers restricting the ability of Lexington County residents to access therapeutic cardiac catheterization services at either Providence or Palmetto.

C. Emergent Cardiac Catheterization Services

40. One of the primary concerns raised by LMC with regard to the accessibility of therapeutic cardiac catheterization services to Lexington County residents is the time and difficulty required to transfer patients from LMC to Providence or Richland for therapeutic cardiac catheterizations, particularly in emergency situations.

41. In 2005, LMC had 73,000 emergency room visits at the main emergency room in its West Columbia hospital, with 7,242 of those emergency room patients presenting with a cardiac diagnosis. Of those 7,242 emergency cardiac patients in 2005, 69 patients—or less than 1% of the patients presenting with cardiac complaints—were transferred to either Providence or Palmetto for emergency cardiac treatment for an acute myocardial infarction, i.e., heart attack. There was no concrete evidence presented at the hearing of this matter suggesting that the health of these transferred emergency patients, or the health of any other cardiac transferees from LMC to Providence and Palmetto, was compromised in any way by the transfers.

42. Further, the consensus of the clinical witnesses presented at the hearing is that the overwhelming majority of therapeutic cardiac catheterizations are scheduled procedures performed on stable patients and that only somewhere between 5% and 10% of cardiac patients require emergency cardiac intervention procedures such as therapeutic catheterizations.

VI. Impact of Lexington's Proposed Program upon Existing Providers in the Midlands

43. Based upon the likely referral patterns of LMC's county-wide network of employed physicians and upon LMC's existing high market share in the county for medical services—and, in particular, its high market share for diagnostic cardiac catheterization services and other cardiovascular services—I find that a comprehensive cardiac services program at LMC will likely capture much, if not most, of the market for open-heart surgery and therapeutic catheterization in Lexington County. In particular, I find that, with such a program, LMC is likely to capture 65% or more of the market in these cardiac services for residents of Lexington County.

44. As noted above, Providence Hospital draws approximately one-fifth of its open-heart surgery and therapeutic cardiac catheterization patients from Lexington County and Palmetto Health Richland draws nearly one-third of its open-heart surgery and therapeutic catheterization patients from Lexington County. By capturing some two-thirds of these patients, a comprehensive cardiac program located at LMC will jeopardize these substantial patient bases for the programs at Providence and Palmetto and significantly reduce the number of open-heart and therapeutic catheterization procedures performed at those hospitals. Such reductions in the number of open-heart surgeries and therapeutic cardiac catheterizations will have several, serious adverse consequences for the cardiac programs at Providence and Palmetto.

45. The potential reductions in the number of open-heart surgeries performed at Providence and Palmetto would adversely affect the quality of care provided in those programs. With the loss of the open-heart surgery cases captured by LMC, the annual volume of open-heart surgeries performed at both Providence and Palmetto would fall below 200 open-heart surgeries per suite, and thus both programs would fall below the minimum number of surgeries the Department considers necessary to maintain a program's proficiency and overall quality of care.

46. The potential reductions in the number of open-heart surgeries and therapeutic catheterizations performed at Providence and Palmetto would also have a substantial adverse financial impact upon the cardiac programs at those hospitals. Based upon the expert testimony presented at the hearing, the financial impact of these lost procedures would likely be a total annual loss of approximately eight million dollars for Providence and between 3.2 million and 4.5 million dollars for Palmetto. These financial losses would be magnified by the significant capital expenditures that both facilities have made in recent years to expand their cardiac services, including, most notably, the 77-million-dollar heart hospital opened by Palmetto in January 2006.

47. Further, the establishment of an open-heart surgery and therapeutic catheterization program at LMC would adversely impact the quality of care at existing programs in the Midlands by drawing highly trained, specialized medical staff, such as cardiovascular anesthesiologists and cardiac surgery nurses, away from those programs. Such highly qualified and highly skilled staff are critical to the provision of quality cardiac care in these programs, and the loss of such personnel

would have an adverse effect on the existing providers' ability to maintain the quality of their programs.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, I conclude the following as a matter of law:

I. Jurisdiction, Burden of Proof, and the Weight and Sufficiency of Evidence

1. This Court has jurisdiction over this contested case proceeding pursuant to S.C. Code Ann. §§ 1-23-310 et seq. (2005), S.C. Code Ann. § 1-23-600(B) (Supp. 2005), S.C. Code Ann. § 44-7-210(E) (2002), and 24A S.C. Code Ann. Regs. 61-15, § 403 (Supp. 2005).

2. The contested case hearing conducted before this Court in a CON matter is a trial *de novo*, "in which 'the whole case is tried as if no trial whatsoever had been had in the first instance,'" and the administrative law judge conducting the hearing is the sole fact-finder, who "must make sufficiently detailed findings supporting the denial or grant of a permit application." Marlboro Park Hosp. v. S.C. Dep't of Health & Envtl. Control, 358 S.C. 573, 579, 595 S.E.2d 851, 854 (Ct. App. 2004) (quoting from Blizzard v. Miller, 306 S.C. 373, 412 S.E.2d 406 (1991) and Converse Power Corp. v. S.C. Dep't of Health & Envtl. Control, 350 S.C. 39, 564 S.E.2d 341 (Ct. App. 2002), respectively).

3. LMC, as the moving party in this matter, bears the burden of proof in this contested case. S.C. Code Ann. § 44-7-210(E) (2002); 24A S.C. Code Ann. Regs. 61-15, § 403(1) (Supp. 2005); see also Leventis v. S.C. Dep't of Health & Envtl. Control, 340 S.C. 118, 132-33, 530 S.E.2d 643, 651 (Ct. App. 2000) (holding that the burden of proof in administrative proceedings generally rests upon the party asserting the affirmative of an issue); 2 Am. Jur. 2d Administrative Law § 354 (2004) (same). Therefore, LMC must prove, by a preponderance of the evidence, that the Department improperly denied its application for a CON to establish an open-heart surgery and therapeutic cardiac catheterization program at its West Columbia hospital. See Anonymous v. State Bd. of Med. Exam'rs, 329 S.C. 371, 375, 496 S.E.2d 17, 19 (1998) (holding that the standard of proof in an administrative proceeding is generally the preponderance of the evidence); see also Nat'l Health Corp. v. S.C. Dep't of Health & Envtl. Control, 298 S.C. 373, 379, 380 S.E.2d 841, 844 (Ct. App. 1989) (holding that the preponderance of the evidence standard applies in CON disputes).

4. The preponderance of the evidence "is evidence which is of greater weight or more convincing than the evidence which is offered in opposition to it; that is, evidence which as a whole shows that the fact sought to be proved is more probable than not." Black's Law Dictionary 1182 (6th ed. 1990). "The preponderance of the evidence means such evidence, as when considered and compared with that opposed to it, has more convincing force and produces in the mind the belief that what is sought to be proved is more likely true than not true." Alex Sanders & John S. Nichols, Trial Handbook for South Carolina Lawyers § 9.5, at 371 (2d ed. 2001) (citing to Frazier v. Frazier, 228 S.C. 149, 89 S.E.2d 225 (1955)).

5. The test for the sufficiency of a proffer of evidence to warrant a finding is as follows:

> A verdict or finding must be based on the evidence and must be based on the facts proved. Under this well established rule, although difficulty of proof does not prevent the assertion of a legal right, the verdict or finding cannot rest on surmise, speculation, or conjecture. Furthermore, a verdict of the jury or a finding of the court cannot be supported only by guesswork. Also, it has been said that the verdict or finding cannot rest on supposition, assumption, imagination, suspicion, arbitrary action, whim, percentage, or conclusions that are in conflict with undisputed fact.
>
> The evidence on which the verdict or finding is based must be competent, legal evidence received in the course of the trial, credible, and of probative force, and must support every material fact. The decision should be against the party having the burden of proof where there is no evidence, or the evidence as to a material issue is insufficient[.]

32A C.J.S. Evidence § 1339, at 757-58 (1996); see also S.C. Code Ann. § 1-23-320(i) (2005) ("Findings of fact shall be based exclusively on the evidence and on matters officially noticed."). Probative evidence is "[e]vidence that tends to prove or disprove a point in issue." Black's Law Dictionary 579 (7th ed. 1999).

6. The weight and credibility assigned to evidence presented at the hearing of a matter is within the province of the trier of fact. See S.C. Cable Television Ass'n v. S. Bell Tel. & Tel. Co., 308 S.C. 216, 222, 417 S.E.2d 586, 589 (1992). Furthermore, a trial judge who observes a witness is in the best position to judge the witness's demeanor and veracity and to evaluate the credibility of his testimony. See, e.g., Woodall v. Woodall, 322 S.C. 7, 10, 471 S.E.2d 154, 157 (1996); Wallace v. Milliken & Co., 300 S.C. 553, 556, 389 S.E.2d 448, 450 (Ct. App. 1990).

7. The South Carolina Rules of Evidence are applicable to this contested case proceeding. See S.C. Code Ann. § 1-23-330(1) (2005). Under those rules, "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." Rule 702, SCRE. An expert is granted wide latitude in determining the basis of his or her opinion, and where an expert's testimony is based upon facts sufficient to form an opinion, the trier of fact must weigh its probative value. Small v. Pioneer Machinery, Inc., 329 S.C. 448, 470, 494 S.E.2d 835, 846 (Ct. App. 1997).

8. "[E]xpert testimony is essential in cases which involve a subject of special technical science, skill, or occupation of which the members of the jury or the trial court are not presumed to be specially informed." 32A C.J.S. Evidence § 729, at 85 (1996). For example, the South Carolina Supreme Court has held that, in medical malpractice cases, "the plaintiff must use expert testimony . . . unless the subject matter lies within the ambit of common knowledge and experience, so that no special learning is needed to evaluate the conduct of the defendant." Pederson v. Gould, 288 S.C. 141, 143, 341 S.E.2d 633, 634 (1986).

9. In general, "expert opinion evidence is to be considered or weighed by the triers of the facts like any other testimony or evidence . . . [;] the triers of fact cannot, and are not required to, arbitrarily or lightly disregard, or capriciously reject, the testimony of experts or skilled witnesses, and make an unsupported finding to the contrary of the opinion." 32A C.J.S. Evidence § 727, at 82-83 (1996). However, the trier of fact may give an expert's testimony the weight he or she determines it deserves. Florence County Dep't of Soc. Servs. v. Ward, 310 S.C. 69, 72-73, 425 S.E.2d 61, 63 (Ct. App. 1992). Further, the trier of fact may accept the testimony of one expert over that of another. See S.C. Cable Television Ass'n v. S. Bell Tel. & Tel. Co., 308 S.C. 216, 417 S.E.2d 586 (1992).

II. Certificate of Need Program

10. As referenced in the Findings of Fact, South Carolina regulates the distribution of certain major health care facilities and services throughout the state under a Certificate of Need program administered by DHEC. See S.C. Code Ann. §§ 44-7-110 through 44-7-370 (2002 & Supp.

2005) (setting out the "State Certification of Need and Health Facility Licensure Act"). The purpose of this regulatory scheme is to "promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State." S.C. Code Ann. § 44-7-120 (2002).

11. Under this regulatory program, a health care facility is required to obtain a Certificate of Need (CON) from DHEC prior to undertaking, among other things, "a capital expenditure by or on behalf of a health care facility which is associated with the addition or substantial expansion of a health service for which specific standards or criteria are prescribed in the State Health Plan." S.C. Code Ann. § 44-7-160(4) (2002); 24A S.C. Code Ann. Regs. 61-15, § 102(1)(d) (Supp. 2005). Open-heart surgery and therapeutic cardiac catheterization are services for which the 2003 State Health Plan contains specific standards and criteria and, therefore, a health care facility is required to obtain a CON from the Department prior to establishing or substantially expanding such services. See DHEC Ex. #2, at II-33 through II-53 (setting forth standards, definitions, and licensing criteria for cardiac catheterization and open-heart surgery services); see also DHEC Ex. #2, at II-48 ("The establishment or addition of an open heart surgery unit requires Certificate of Need review, as this is considered a substantial expansion of a health service.").

12. In determining whether to issue a CON to an applicant, the Department evaluates the proposed health care service or facility under the licensure standards and criteria set out in the State Health Plan for the particular service or facility and under the general project review criteria set out in Section 802 of Regulation 61-15. See S.C. Code Ann. § 44-7-210(C) (2002); 24A S.C. Code Ann. Regs. 61-15, § 307(1) (Supp. 2005). Accordingly, the Department may not issue a CON unless the application for the proposed project complies with *both* the State Health Plan *and* the regulatory project review criteria. See S.C. Code Ann. § 44-7-210(C) (2002); 24A S.C. Code Ann. Regs. 61-15, § 307(1) (Supp. 2005). Therefore, while "no project may be approved unless it is consistent with the State Health Plan," 24A S.C. Code Ann. Regs. 61-15, § 801(3) (Supp. 2005), such compliance is not sufficient in itself for the issuance of a CON, and "[t]he Department may refuse to issue a Certificate of Need even if an application is in compliance with the State Health Plan but is

inconsistent with project review criteria or departmental regulations," 24A S.C. Code Ann. Regs. 61-15, § 307(1); see also S.C. Code Ann. § 44-7-210(C). Whether LMC's proposed comprehensive cardiac program complies with these two sets of licensing standards will be discussed, in turn, below.

III. LMC's Compliance with the 2003 State Health Plan

A. State Health Plan Standards for Open-Heart Surgery

13. The 2003 State Health Plan contains detailed definitions, standards, and Departmental findings governing the issuance of Certificates of Need for open-heart surgery and for cardiac catheterization services. See DHEC Ex. #2, at II-33 to II-53. With regard to open-heart surgical services, the Plan sets out ten technical requirements an applicant must satisfy in order to be granted a CON to provide such services. See DHEC Ex. #2, at II-48 to II-50.

14. The first two of these standards reiterate that the establishment or addition of an open-heart surgery unit is a substantial expansion of a health service that requires CON review and that comprehensive cardiac catheterization laboratories, which perform therapeutic cardiac catheterizations, may only be located in hospitals that provide open-heart surgery. DHEC Ex. #2, at II-48 (Standards 1 and 2). In the case at hand, LMC has applied for a CON for its proposed open-heart surgery program and seeks to provide therapeutic cardiac catheterization services only as part of a comprehensive cardiac care program, which includes the proposed open-heart surgery services.

15. Subsequent standards state that the capacity of an open-heart surgery operating room is 500 open-heart surgeries per year and require a hospital to perform a minimum of 200 open-heart surgeries annually in each open-heart surgery unit by its third year of operation. DHEC Ex. #2, at II-48 (Standards 3, 4, and 5.B). Similarly, a hospital may only expand an existing open-heart surgery program if it has operated at 70% capacity for the two years prior to its CON application and can project a minimum of 200 open-heart procedures per year in the new open-heart surgery unit. DHEC Ex. #2, at II-49 (Standard 7). In the instant case, LMC projects that it will perform just over 200 open-heart surgeries in its program by its third year of operation; Respondents project that the number of open-heart surgeries performed at LMC by its third year of operation will be closer to 300 surgeries. In either case, LMC satisfies these standards, although only for one dedicated open-heart

surgery operating room.[4]

16. Additional standards provide that a new open-heart surgery program may only be approved if all existing open-heart surgery providers in the service area, i.e., within a 60-minute one-way drive of the proposed program, are performing an annual minimum of 350 open-heart surgery procedures per open-heart surgery unit and the new program will not cause any of the existing programs to drop below 350 procedures per year for each open-heart surgery unit. See DHEC Ex. #2, at II-48, II-49 (Standards 5.A and 6). However, there is a narrow exception to this requirement, commonly known as the "single county" exception, that allows the establishment of a new open-heart surgery program at a hospital regardless of the number of open-heart surgeries being performed at other programs in the service area, so long as (1) there are no other open-heart surgery programs located in the same county as the proposed program and (2) the proposed facility currently offers cardiac catheterization services and provided a minimum of 1,200 catheterizations in the prior year. DHEC Ex. #2, at II-48 (Standard 5.A).[5] Here, LMC satisfies this single-county exception, and thus satisfies Standards 5.A and 6, because there are no other open-heart surgery providers in Lexington County and LMC performed over 1,200 diagnostic catheterizations in the year preceding its CON application.

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[4] These projections would only authorize LMC to establish *one* open-heart surgery operating room, rather than the *two* rooms it requested in its CON application. The standards in the 2003 State Health Plan clearly require a hospital to project a minimum of 200 open-heart procedures annually for *each* open-heart surgery unit, i.e., operating room, it seeks to establish. See DHEC Ex. #2, at II-48, II-49 (Standards 4, 5.B, and 7); see also DHEC Ex. #2, at II-47 (defining an "open heart surgery unit"). Further, neither the State Health Plan nor the CON Act and regulations authorize or provide standards for a "back-up" open-heart surgery operating room, and, in practice, hospitals simply move open-heart surgery equipment into a standard operating room on those rare occasions in which the dedicated open-heart surgery rooms are unavailable. Therefore, regardless of the prudence of LMC's request for a "back-up" open-heart surgery operating room to supplement its primary open-heart surgery unit, LMC would not be authorized for such an additional open-heart surgery operating room under the State Health Plan unless it can project at least 200 surgeries for the room, which LMC has not done in this case.

[5] While this exception is only explicitly stated with respect to Standard 5.A, it must be read naturally to apply to Standard 6 as well. Any other reading would reach an absurd result in which the prohibition upon causing existing programs to fall below 350 procedures annually in Standard 6 essentially renders the single-county exception a nullity or restricts the exception to apply only in an exceedingly rare set of circumstances.

17. The remaining standards require open-heart programs to adopt standards for treating high-risk patients, to have appropriate physician staffing, both in terms of numbers and proficiency, and to provide the capability to perform emergency coronary artery surgery. DHEC Ex. #2, at II-49 to II-50 (Standards 8, 9, and 10). While LMC's application may not have been as detailed as other applications for open-heart surgery programs with regard to these standards, LMC did provide sufficient information in its application to demonstrate that its program would be able to satisfy these operational standards.

B. State Health Plan Findings and Policies with regard to Open-Heart Surgery

18. In addition to setting forth the technical standards discussed above, the 2003 State Health Plan also contains six specific findings made by the Department regarding the need for open-heart surgery services in South Carolina and a general discussion of the appropriate distribution of open-heart surgery services in the state. See DHEC Ex. #2, at II-35 (general discussion), II-51 to II-52 (specific findings).

19. The six specific findings regarding the need for open-heart surgery services note that "[o]pen-heart surgery services are available within sixty (60) minutes travel time for the majority of residents of South Carolina" and that "most of the open heart surgery providers are currently utilizing less than the functional capability (i.e. 70% of maximum capacity) of their existing surgical suites." DHEC Ex. #2, at II-51 to II-52 (Findings 1 and 2). These findings further recognize that clinical research has shown that "a minimum number of procedures is recommended per year in order to develop and maintain physician and staff competency in performing these procedures" and that "a positive relationship [exists] between the volume of open heart surgeries performed annually at a facility and patient outcomes." DHEC Ex. #2, at II-52 (Findings 3 and 5).

20. Two further findings speak most directly to the issues raised in this case and are particularly relevant to the resolution of this matter. The Department's fourth finding states, in full:

> Increasing geographic access may create lower volumes in existing programs causing a potential reduction in quality and efficiency, exacerbate existing problems regarding the availability of nursing staff and other personnel, and not necessarily reduce waiting time since other factors (such as the referring physician's preference) would still need to be addressed.

DHEC Ex. #2, at II-52 (Finding 4). In a similar vein, the sixth finding reads, as follows:

> The State Health Planning Committee recognizes the important correlation between volume and proficiency. The Committee further recognizes that the number of open heart surgery cases is decreasing and that maintaining volume in programs is very important to the provision of quality care to the community.

DHEC Ex. #2, at II-52 (Finding 6).

21. These findings are echoed in the general discussion of the distribution of open-heart surgical services found in the overview discussion for the Plan's section on cardiac services:

> Both cardiac catheterization and open heart surgery programs require highly skilled staffs and expensive equipment. Appropriately equipped and staffed programs serving larger populations are preferable to multiple, minimum population programs. Underutilized programs are a less efficient use of an expensive resource and often reflect unnecessary duplication of services in an area. This may seriously compromise quality and safety of procedures and increase cost of care. Optimal performance requires a caseload of adequate size to maintain the skills and efficiency of the staff. . . . There should be a minimum of 200 adult open heart surgery procedures performed annually per open heart surgery unit; improved results appear to increase in hospitals that perform a minimum of 350 cases annually.

DHEC Ex. #2, at II-35; see also DHEC Ex. #2, at II-36 (emphasizing that the CON standard of 200 open-heart surgeries per year per surgical suite "should not be interpreted as an optimal level of operation," because such a volume "amounts to less than 5 procedures per week and clearly does not fully utilize the resources required to staff a cardiac surgery program").

22. I find that LMC's proposed open-heart surgery program conflicts with these findings and policies set out in the 2003 State Health Plan. It cannot be overemphasized that, while the establishment of an open-heart surgery program at LMC would minimally increase geographic access for such services, a program at LMC would also significantly reduce volumes in existing providers and exacerbate staffing problems in the area, thus causing a potential reduction in the quality of care in the existing open-heart surgery programs in the Midlands. Crucially, the establishment of an open-heart program at LMC would likely reduce the open-heart surgery volumes at Providence and Palmetto to at or below the minimum threshold for competency in such procedures, i.e., below 200 open-heart surgeries per year per open-heart surgical suite, and would put LMC only marginally above that threshold. As a result, the Midlands would have "multiple, minimum population programs," rather than fewer, larger, and more competent programs as recommended by the State

Health Plan.

23. Therefore, while LMC's CON application generally complies with certain technical standards for open-heart surgical services put forth in the State Health Plan, the project as a whole conflicts with the findings and policies expressed in the Plan regarding the distribution of open-heart surgery services and must ultimately be deemed to be *inconsistent* with the Plan.

IV. LMC's Compliance with Regulatory Project Review Criteria

24. Section 802 of Regulation 61-15 sets out thirty-three project review criteria that are used to review all projects requiring CON approval. Of particular relevance to the case at hand are the project review criteria related to the unnecessary duplication of services and the adverse impact of a project upon existing providers. See 24A S.C. Code Ann. Regs. 61-15, § 802(3)(a), (b) (Supp. 2005) (unnecessary duplication of services), § 802(23)(a), (b) (Supp. 2005) (adverse effects on other facilities).

A. Unnecessary Duplication of Existing Services

25. Criteria 3(a) and 3(b) in Section 802 of Regulation 61-15 provide that the "[u]nnecessary duplication of services and unnecessary modernization of services will not be approved" and that a "proposed service should be located so that it may serve medically underserved areas (or an underserved population segment) and should not unnecessarily duplicate existing services or facilities in the proposed service area." 24A S.C. Code Ann. Regs. 61-15, § 802(3)(a), (b). In its denial of LMC's application, the Department found that LMC's proposed open-heart surgery program would violate these project review criteria by unnecessarily duplicating existing open-heart surgical services provided at Providence and Palmetto. See DHEC Ex. #1, at 846. This determination must be sustained. With three existing open-heart surgery providers within LMC's service area, each of which has greater than 50% *excess* capacity for open-heart surgery procedures, and with the overall use rate for open-heart surgery declining, LMC's proposed open-heart surgery program would constitute an unnecessary duplication of those services and is, therefore, inconsistent with Section 802(3)(a) and (3)(b) of Regulation 61-15. Further, given the number of Lexington County residents that receive open-heart surgical services at Providence and Palmetto and the high overall use rate for open-heart surgery among Lexington County residents, LMC's proposed open-

heart surgery program will not serve a medically underserved area, but rather, will constitute an unnecessary duplication of existing open-heart surgery services in the Midlands. Accordingly, LMC's proposed project is further inconsistent with Section 802(3)(b).

B. Adverse Impact upon Existing Providers

26. Criterion 23(a) of Section 802 addresses the adverse impact of a proposed project upon existing facilities in the area and requires that "[t]he impact on the current and projected occupancy rates or use rates of existing facilities and services should be weighed against the increased accessibility offered by the proposed services." 24A S.C. Code Ann. Regs. 61-15, § 802(23)(a). In its denial of LMC's application, the Department found that LMC's proposed open-heart surgery program would violate this project review criterion by having an adverse impact on the current and projected use rates of the existing open-heart surgery programs at Providence and Palmetto. See DHEC Ex. #1, at 846. This determination must be sustained. The establishment of an open-heart surgery program at LMC would draw a significant number of patients from existing providers and drive open-heart surgery volumes at those providers below the recommended level to maintain quality of care, while only providing a minimal increase in geographic accessibility for open-heart surgical services in the Midlands.

27. Further, criterion 23(b) of Section 802 states that "[t]he staffing of the proposed service should be provided without unnecessarily depleting the staff of existing facilities or services or causing an excessive rise in staffing costs due to increased competition." 24A S.C. Code Ann. Regs. 61-15 § 802(23)(b). While the Department did not cite to Section 802(23)(b) in its denial of LMC's application, the competition for staffing created by the establishment of an open-heart surgery program at LMC would have an adverse impact upon existing open-heart surgery providers in the Midlands. This new program would likely draw critical staff away from existing programs and, at the very least, increase the staffing costs of existing providers as they seek to replace and retain the highly skilled and specialized staff necessary for the operation of an open-heart surgery program.

28. Therefore, LMC's proposed open-heart surgery program is also inconsistent with the adverse impact project review criteria found at Section 802(23) of Regulation 61-15.

29. In sum, regardless of whether or not LMC complies with the State Health Plan, these inconsistencies with the regulatory project review criteria related to the unnecessary duplication of services and the adverse impact upon existing providers are grounds, in and of themselves, upon which to deny LMC's CON application. See S.C. Code Ann. § 44-7-210(C); 24A S.C. Code Ann. Regs. 61-15, § 307(1).

V. Conclusion

30. While LMC's proposed open-heart surgery program satisfies certain technical standards for such services set out in the 2003 State Health Plan (at least for a single open-heart surgery unit), the proposed program is inconsistent both with the findings and policies for the distribution of open-heart surgery programs set out in the Plan and with the regulatory project review criteria regarding the unnecessary duplication of existing services and the adverse impact of a proposed service upon existing providers. Accordingly, the Department's decision to deny LMC's CON application to provide open-heart surgery at its West Columbia hospital must be sustained.

31. Further, because LMC does not qualify for a CON to perform open-heart surgery, its joint CON application to perform therapeutic cardiac catheterizations must also be denied, as such services may only be provided in a hospital that has an open-heart surgery program. See DHEC Ex. #2, at II-39, II-48 (providing under the 2003 State Health Plan, in Standard 7 for cardiac catheterization services and Standard 2 for open-heart surgical services, that the lack of a formal open-heart surgery program at a hospital is an "absolute contraindication" for the hospital to perform therapeutic cardiac catheterizations).

32. Finally, it must be noted that this Court does not operate in a vacuum and is well aware of the social and political wrangling that has occurred regarding LMC's application for a CON to provide comprehensive cardiac services. However, while I am sensitive to the concerns raised by interested parties on both sides of this issue, I do not possess unfettered discretion such that I can, by judicial fiat, decide whether LMC should be authorized to perform open-heart surgery. Rather, in reaching a decision in this matter, I am constrained by the evidentiary record presented through the conduct of the trial in this case and by the applicable law. In particular, it must be emphasized that the South Carolina General Assembly has chosen to closely regulate the distribution of certain health

care facilities and services, including open-heart surgery and cardiac catheterization, under a comprehensive Certificate of Need program consisting of the CON Act, its accompanying regulations, and the State Health Plan. It is the standards set forth under that regulatory program that I am bound to apply in this matter. And, under those standards, the conclusion is inescapable that LMC's proposed open-heart surgery services, if authorized, would constitute an unnecessary duplication of existing open-heart surgical services in the Midlands and would have an unduly adverse impact upon existing providers of open-heart surgery in the area.

Never has it been more true in an administrative case that a judge "ought to live an eagle's flight beyond the reach of fear or favor, praise or blame, profit or loss." William S. McFeely, Frederick Douglass 318 (1991) (quoting Douglass's disappointed response to the United States Supreme Court's 1883 decision in The Civil Rights Cases). When this case is viewed in such an impartial light, the Department's decision to deny LMC's CON application must be sustained.

ORDER

Based upon the Findings of Fact and Conclusions of Law stated above,

IT IS HEREBY ORDERED that the Department's decision to deny Petitioner Lexington Medical Center's CON application for the development of an open-heart surgery program and therapeutic cardiac catheterization program at its hospital in West Columbia, South Carolina, is **SUSTAINED.**

AND IT IS SO ORDERED.

JOHN D. GEATHERS
Administrative Law Judge
1205 Pendleton Street, Suite 224
Columbia, South Carolina 29201-3731

September 15, 2006
Columbia, South Carolina

CERTIFICATE OF SERVICE
This is to certify that the undersigned has this date served this order in the above entitled action upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, or in the Interagency Mail Service addressed to the party(ies) or their attorney(s).
This 15th day of September 2006
By: Judicial Law Clerk

AN OVERVIEW OF THE ADMINISTRATIVE LAW COURT DECISION TO DENY LEXINGTON MEDICAL CENTER'S CON APPLICATION FOR OPEN HEART SURGERY

EXECUTIVE SUMMARY:

The Administrative Law Judge rejected every argument set forth by Lexington Medical Center (LMC) to support the approval of an Open Heart Surgery Program at LMC and adopted (in even stronger language than DHEC) the reasons set forth by Providence, Palmetto Richland and DHEC. Specifically, the Judge found the following:

- An Open Heart program at LMC would violate the policy of the State of South Carolina set forth in the State Health Plan and the Certificate of Need statute.
- There were no patients whose health was compromised because LMC did not have an Open Heart program. In other words, he found that no one had died or had any negative health consequences because of a transfer to Providence or Palmetto for open heart surgery or a therapeutic catheterization during a heart attack.
- An Open Heart program at Lexington Medical Center would reduce the quality of care to patients at Providence, Palmetto Richland, and Aiken.
- Advances in medical science have significantly reduced the number of open heart surgeries performed in South Carolina and the midlands since 2000 and as a result, the number of open heart surgeries will decline or remain stagnant even with an increase in population.
- An Open Heart program at LMC was an unnecessary duplication of services because of the significant unused capacity at each hospital to perform open heart surgery and therapeutic catheterizations.
- Lexington County residents have access to these services at Providence and Palmetto and there are no barriers for Lexington County residents to receive open heart surgery services or therapeutic catheterization services at the two hospitals in Columbia.
- An Open Heart program at LMC would have a significant financial adverse impact to Providence and Palmetto and would have a negative effect by hiring away qualified staff.

SISTERS OF CHARITY
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2008-2009 South Carolina State Health Planning Committee Meeting

March 2008

LMC's Proposed Amendments to Open Heart Surgery Standards

LMC's Proposed Amendments

- The proposed to changes to the Open Heart Surgery Standards are a single hospitals' attempt to overcome insurmountable obstacles identified by both DHEC and the Administrative Law Judge during the review of LMC's CON application.
- The suggested changes do not have a sound health planning basis and create inconsistencies on the State Health Plan.

LMC's Proposed Amendments

- Proposed changes to Standard 5 modify the utilization measure from per OHS room to per OHS program.
  - The is inconsistent with other sections of the Health Plan
    - Capacity is defined as 500 procedures per room. (Standard 3 – p.II-52)
    - To determine if existing providers have capacity, utilization per room is critical.
    - Occupancy threshold per unit (room) is used to determine need for expansion of an existing provider (Standard 7 – p.II-53) not per program.

LMC's Proposed Amendments

- Proposed language allows a new provider to develop multiple OHS rooms in their initial application.
  - *"An applicant must project that the propose service will perform a minimum of 200 adult open heart surgery procedures annual per open heart surgery program..."*
- Not sound health planning to ignore the capacity of existing providers when determining need or impact.

– Other states (NC and Virginia) also use per OHS room standards to determine need.

LMC's Proposed Amendments

- **Proposed changes to Standard 6 create a unique exception standard that would only apply to one provider in the state – Lexington Medical Center.**
  - **Proposed language globally disregards ALL other OHS standards.**
    - **There is no health planning basis for using the number of licensed acute beds or ER visits as an indicator for potential Open Heart Surgery volumes.**
      - **Emergent cardiac ER visits would be an indicator**
    - **The 1,200 diagnostic threshold is arbitrary and outdated.**

Standard 6: Exception Measures –Ignoring single county provider

S.C. Diagnostic Catheterization Providers
2006 Statistics

	Beds	Cath Volume	ED Visits	Additional Beds Needed
1 Lexington Medical Center	384	1,355	71,230	0
2 Palmetto Health Baptist	363	365	32,934	0
3 Tuomey Hospital	283	331	52,074	17
4 RMC Orangeburg - Calhoun	247	691	50,222	53
5 Conway Hospital	210	763	40,604	90
6 Bon Secours St. Francis Xavier	204	21	37,720	96
7 Springs Memorial Hospital	199	382	28,219	101
8 Mary Black Memorial	176	213	26,987	124
9 Beaufort Memorial Hospital	169	397	34,767	131
10 Oconee Memorial Hospital	169	993	36,669	131
11 Loris Community Hospital	155	318	38,238	145
12 Georgetown Memorial Hospital	131	915	27,949	169
13 Kershaw County Medical Center	121	0	22,258	179
14 Carolina Pines Regional Medical Center	116	322	31,127	184
15 Palmetto Baptist Med Ctr - Easley	109	567	33,750	191

Source: 2006 Joint Annual Reports, 2008-2009 Draft State Health Plan.

With the exception of Tuomey, other providers would need to experience a 21% to 175% increase in licensed beds to reach bed threshold.

Standard 6: Exception Measures –Ignoring single county provider

S.C. Diagnostic Catheterization Providers
2006 Statistics

	Beds	Cath Volume	ED Visits	Additional Beds Needed
1 Lexington Medical Center	384	1,355	71,230	0
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13 Mary Black Memorial	176	213	26,987	124
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15 Kershaw County Medical Center	121	0	22,258	179

Source: 2006 Joint Annual Reports, 2008-2009 Draft State Health Plan.

Other providers would need to experience 20% to 5600% increase in utilization to reach catheterization volume threshold.

Standard 6: Exception Measures –Ignoring single county provider

S.C. Diagnostic Catheterization Providers
2006 Statistics

	Beds	Cath Volume	ED Visits	Additional Beds Needed
1 Lexington Medical Center	384	1,355	71,230	0
2 Tuomey Hospital	283	331	52,074	17
3 RMC Orangeburg - Calhoun	247	691	50,222	53
4 Conway Hospital	210	763	40,604	90
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14 Mary Black Memorial	176	213	26,987	124
15 Kershaw County Medical Center	121	0	22,258	179

Source: 2006 Joint Annual Reports, 2008-2009 Draft State Health Plan.

Other providers would need to experience 25% to 192% increase in ED utilization to reach volume threshold. 1992 ED visits for Tuomey totaled approx. 41,000 and TRMC was 33,677.

C-PORT Study

C-PORT Study

- Any amendment to allow for elective angioplasty should not be considered by the Planning Committee.
  - While some states have allowed this to occur in their state, it has been after significant study and consideration.
    - Georgia is the most recent state to allow participation.
      - Topic was discussed over multiple years.
      - Significant opposition existed and continues to exist.
      - Main goal of the program was to assure access in rural areas without Open Heart Surgery providers.
        - Only 1 of 10 was located less than 40 miles from existing providers – it was in suburban Atlanta and is a Sister Hospital to existing OHS providers.
  - Only two providers have applied for emergency PCI approval in South Carolina.

C-PORT Study

- C-PORT outcome measure is DEATH.
- Study does not consider need for additional providers of elective angioplasty.
- Study does not consider impact on existing comprehensive providers.
- Approval of C-PORT is South Carolina would not have a positive impact on cost, quality or access – In fact it would negatively impact existing providers.

#14
Mac Leopard, MD – Thoracic and Cardiovascular Associates

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February 29, 2008

Mr. Les Shelton
Division of Planning and Certificate of Need
South Carolina Department of Health
and Environmental Control
The South Carolina Health Planning Committee
1777 St. Julian Place, Suite 201
Columbia, SC 29204

RE: Draft 2008-2009 South Carolina Health Plan

Dear Mr. Shelton and Committee Members:

Thank you for the opportunity to submit written comments to the 2008-2009 South Carolina Health Plan (the "Plan"). In this letter, I will primarily address two areas of the Plan. First, I will discuss the provision of cardiovascular services in general. Second, I will discuss the proposed language found in Standard (9) of the Standards for Cardiac Catheterization.

As a cardiothoracic and vascular surgeon performing open heart surgery and other cardiovascular procedures at Sisters of Charity Providence Hospitals ("Providence") and in the Midlands area of South Carolina for almost 25 years, I am in a unique position of having first-hand knowledge of the issues related to the provision of cardiovascular services to the citizens of South Carolina.

There are currently 17 open heart surgery providers in South Carolina. These programs are spread out geographically to ensure that that all citizens have rapid access to comprehensive cardiac care services, including open heart surgery. These providers are within 60 minutes travel time of the majority of residents of South Carolina.

South Carolina's open heart surgery providers are facing declining volumes and increasing excess capacity. Before 1998, the number of open heart surgery procedures performed at Providence climbed at a steady rate. Since 1998, however, there has been a steady decline in the number of open heart surgery performed. This decline has also occurred across South Carolina and the entire nation. In 1998, Providence performed around 1,150 open heart surgery procedures. Last year, it performed 826. That represents a decline of almost 30%. There are various reasons for this decline. The primary reason is advances in cardiology, both in the

medical management of people with coronary artery disease and public health awareness initiatives. The invention of the drug-eluding stent is the most recent device that is being increasingly used on patients that would have received open heart surgery less than a decade ago. In addition, because of changes in technology, emergency open heart surgery almost never occurs. These patients generally receive emergency angioplasty.

There is also significant excess capacity in the existing open surgery programs. The capacity of an open heart surgery unit is 500 procedures annually. In 2006, there were a total of 35 open heart surgery units in operation in South Carolina. Thus, the statewide capacity is 17,500 open heart procedures. In 2006, there were 5,438 procedures. This equates to a statewide average utilization rate of 31.1%. Providence, the largest and busiest open heart surgery provider in the state, had a utilization rate of 41%. These factors can contribute to compromised patient outcomes and, therefore, all efforts must be made to stop this trend.

I understand that Lexington Medical Center ("LMC") may propose an amendment to the Plan that would provide a special exception to the existing open heart surgery standards that would apply to LMC only and would essentially create a carve-out for them to develop an open heart surgery program. This would be totally inconsistent with prudent health planning in light of the current excess open heart surgery capacity in the Midlands and statewide. It is also inconsistent with the declining trend in the number of open heart surgeries and the applicable CON statutes and regulations, particularly in the area of unnecessary duplication and adverse impact. Finally, and most important, this would certainly not be in the best interest of quality patient care. In addition to causing a further decline in the volumes of existing providers, the addition of new open heart programs would dilute the limited personnel resources which also affects quality and increases health care cost. There is simply no clinical or health planning basis to allow for the development of another open heart surgery provider in South Carolina. This issue has been thoroughly reviewed and rejected by clinicians, health regulators, judges, the Legislature and the Governor, and we should respect the consistent theme of this review and reject any attempt by LMC to insert a self-serving carve-out in the Plan.

I would also like to comment on Standard (9) of the Standards for Cardiac Catheterization. This new standard would allow up to three hospitals to participate in the Atlantic C-PORT II Trial. As a preliminary manner, the American College of Cardiology and the American Heart Association have stated that elective/non-primary percutaneous coronary intervention (PCI) or angioplasty should not be performed without open heart surgical back up.

The majority of South Carolina citizens live within 90 minutes of providers who perform elective angioplasty. Most are substantially closer. All of these citizens have timely access to elective angioplasty. For those instances where emergencies arise, DHEC has already provided for a CON to perform emergency angioplasty. The Plan finds that significant catheterization capacity exists in most areas of the state and the benefits of improved accessibility will not outweigh the adverse effects of duplication for angioplasty in South Carolina.

Angioplasty can have serious and life-threatening complications. Without on-site open heart surgical backup, any complications could result in death for the patient. It is inconceivable to me as a cardiac surgeon that South Carolina would subject patients to a study that is inconsistent

with the Plan, subjects patients to a procedure that is considered unsafe and not recommended by the American College of Cardiology and the American Heart Association and that could cause severe harm or even death if one of the many known complications occurs. It is even more inconceivable that this sub-standard of care procedure will be performed when the standard of care is offered at hospitals within one hour drive time.

I am unaware of any instance where South Carolina has ever allowed a research study to become part of the state health plan process. Due to the very nature of the study, it is very possible that these risky and unproven procedures will invariably be performed on patients from low-income, rural parts of our state. This state should be concentrating on ways to ensure that these patients have access to life-saving procedures such as emergency angioplasty instead of subjecting them to a study to determine if elective procedures that they can have performed quickly and safely at other hospitals can be performed. It simply is not worth the risk.

The sole proponent of the C-PORT study recommended that the 30 minute drive time limitation be removed. This recommendation conflicts with the primary purpose of the C-PORT study: Improving access. If a hospital has an existing provider within 30 minutes one way drive time, there is clearly no access issue for that hospital, and it should not be allowed to participate in the C-PORT study.

For these reasons, I do not support the inclusion of the C-PORT study in the Plan and strongly oppose any efforts by LMC or any other party from amending the open heart surgery standards to allow for the development of another open heart surgery program outside of the current accepted standards.

Again, thank you for the opportunity to provide these comments.

Sincerely,

Mac Leppard, M.D.

#15
Lanneau Lide, MD – South Carolina Heart Center

SOUTH CAROLINA HEART CENTER

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Patrick A. X. Hall, M.D.
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Norma M. Khoury, M.D.
Robert G. Kiger, M.D.
Lanneau D. Lide, M.D.
Bashir A. Lone, M.D.
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February 29, 2008

Mr. Les Shelton
Division of Planning and Certificate of Need
South Carolina Department of Health
and Environmental Control
The South Carolina Health Planning Committee
1777 St. Julian Place, Suite 201
Columbia, SC 29204

RE: Draft 2008-2009 South Carolina Health Plan

Dear Mr. Shelton and Committee Members:

I am an interventional cardiologist who has practiced in the Midlands community for 26 years. I would like to take this opportunity to provide written comments to the proposed language found in Standard (9) of the Standards for Cardiac Catheterization in the 2008-2009 Draft South Carolina Health Plan.

Standard (9) of the Health Plan would grant South Carolina hospitals a waiver which would permit them to participate in the C-PORT study and to perform elective percutaneous coronary intervention ("PCI") on patients even though the hospital does not have on-site open heart surgery. Currently, the Health Plan does not allow hospitals to perform non-emergency PCI unless the hospital has on-site open heart surgery capabilities.

The C-PORT study is testing the hypothesis that outcomes of elective PCI performed at hospitals without on-site cardiac surgery are not inferior to outcomes at hospitals with on-site surgery. It uses mortality six weeks after PCI as the primary outcome data, and is also collecting and analyzing additional outcomes data for a nine-month interval, including the comparative incidence of death, heart attack, stroke, bleeding, heart failure, bypass surgery, vascular surgery, and target vessel revascularization, among others. Essentially, the C-PORT study is being undertaken to see if patients will die or be permanently impaired if they receive elective angioplasty at hospitals without open heart surgical backup.

The American College of Cardiology and the American Heart Association (ACC/AHA) have issued guidelines warning against performing elective PCI at institutions without on-site open heart surgery programs. The ACC/AHA guidelines are considered the foremost authority on cardiac care. The ACC/AHA has concluded that performance of elective PCI in a setting without immediately available on-site cardiac surgery potentially compromises patient safety, exposing the patient "to a small but very real additional and medically unnecessary risk." They further conclude that rapid transfer strategies are unrealistic because they are logistically difficult to achieve and require that a critically ill patient be transported outside of a hospital environment, possibly without a physician in attendance. Furthermore, if an institution without cardiac surgery is sufficiently close to one that provides surgery to permit a timely transfer, the guidelines state there is little justification for not transferring the patient electively in the first place.

The C-PORT study should not be included in the Health Plan and should not be approved for a number of reasons. First and foremost, the C-PORT study would allow hospitals to perform procedures that are documented as unsafe for facilities without on-site surgical backup. While the complications involving PCI are rare, they do happen, and when they do, immediate surgical intervention is required. Second, South Carolina citizens do not have any problems with access to PCI procedures. The draft Health Plan finds that significant catheterization capacity exists in most areas of the state and the benefits of improved accessibility will not outweigh the adverse effects of duplication for PCI in South Carolina. Third, the C-PORT study has inherent deficiencies that compromise its ability to be successful. There have been repeated questions about its level of funding and as of early 2007 (no data is available beyond then), only 2,000 patients have enrolled in the study. This is substantially lower than the 16,000 patients the study anticipated ultimately enrolling and it is clear that the study is well behind in its enrollment goals.

The majority of South Carolina citizens live within 90 minutes of existing PCI providers. Most are substantially closer. All of these citizens have timely access to elective PCI. For those instances where emergencies arise, DHEC has already provided for a CON to perform emergency angioplasty. South Carolina providers can perform emergency PCI as needed in order to increase access to life-saving medical procedures.

Allowing a waiver for hospitals to perform elective PCI also does not consider the adverse effects on existing PCI providers and the creation of unnecessary duplication of services. The Health Plan is designed to prevent the proliferation of health care services that are unneeded and that would result in unnecessary duplication. These proposed services are not needed and are potentially unsafe for our citizens. The Health Plan is designed to protect South Carolina's patients and this is especially true for cardiac services where there is proven direct correlation between volume of procedures and quality. As South Carolina does not have an access issue for elective PCI and hospitals already have the ability to provide emergency PCI, the risk associated with providing elective PCI without on-site open heart surgery back up is unnecessary.

As written, to allow hospitals to participate in C-PORT, the Health Plan correctly requires that any participant also apply for a CON to perform emergency PCI. Unfortunately, very few hospitals in South Carolina have applied for the ability to perform this life-saving procedure. Emergency PCI programs are expensive to develop and generate relatively low revenue. For this reason, hospitals do not want to develop these programs. From a clinical standpoint, it is counterintuitive for a hospital to want to provide elective PCI and not provide emergency PCI. The C-PORT standards also correctly exclude participation by hospitals that are within 30 minutes drive time of an existing provider. This geographic limitation is necessary in that if there is an existing provider within a 30 minute drive time, there is clearly no access issue.

I sincerely hope that the Committee will keep patient safety in mind and reject the C-PORT study. Thank you for the opportunity to present you with my comments.

Sincerely,

Lanneau Lide, M.D.

#16
Micheal Biediger – Lexington Medical Center

Lexington Medical Center
Your partner for health and wellness ®

2720 Sunset Boulevard
West Columbia, SC 29169
(803) 791-2000

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February 28, 2008

Gerald A. Wilson, M.D.
Chairman
South Carolina Health Planning Committee
Division of Planning and Certification of Need
2600 Bull Street
Columbia, South Carolina 29201

Re: Revisions to Draft *2008 State Health Plan*

Dear Dr. Wilson:

As you know, when Department Staff prepared the draft *2008-2009 State Health Plan*, they unilaterally removed language from the draft *2007 Plan* concerning open heart surgery services. In response to the State Health Planning Committee's call for public comments on the draft *2008-2009 State Health Plan*, and in follow up to previous correspondence, Lexington Medical Center urges the Committee to amend the Certificate of Need Standards for Open Heart Surgery to reinsert the originally approved language.

Specifically, Lexington Medical Center requests that Standards (5) and (6) of the draft *2008-2009 Plan*, pages II-53 and II-54, be amended to restore the clarification that, when a provider meets the requirements of the single county exception, the exception must be applied to favor access to critical open heart services over the potential adverse effects on other providers outside the county. As Exhibit "A" to this letter, Lexington Medical Center has attached its proposed amendment as set forth in the draft *2007 Plan*.

As you aware, the State Health Planning Committee voted **unanimously** to approve this clarifying language in the draft *2007 State Health Plan* after Lexington Medical Center's application for a Certificate of Need to provide comprehensive cardiac services was denied despite Lexington Medical Center's meeting the single county exception. As recognized by the unanimous vote of the Committee on the previous draft *Plan*, the single county exception seeks to strike a balance between access to care and the impact of additional programs on existing facilities. Thus, the single county exception is limited in scope to sole facilities serving an entire county and applies only when those facilities have reached a critical mass of diagnostic catheterizations. The amendment unanimously approved by the Committee in the draft *2007 Plan* reinforces and clarifies the Committee's previous affirmation of the need for access to these critical services when the requirements of the exception are met.

Thus, Lexington Medical Center strongly urges the State Health Planning Committee to follow its previous course and to revise Standards (5) and (6) of the Certificate of Need Standards for Open Heart Surgery in accordance with the attached amendment. Thank you for your consideration of Lexington Medical Center's comments.

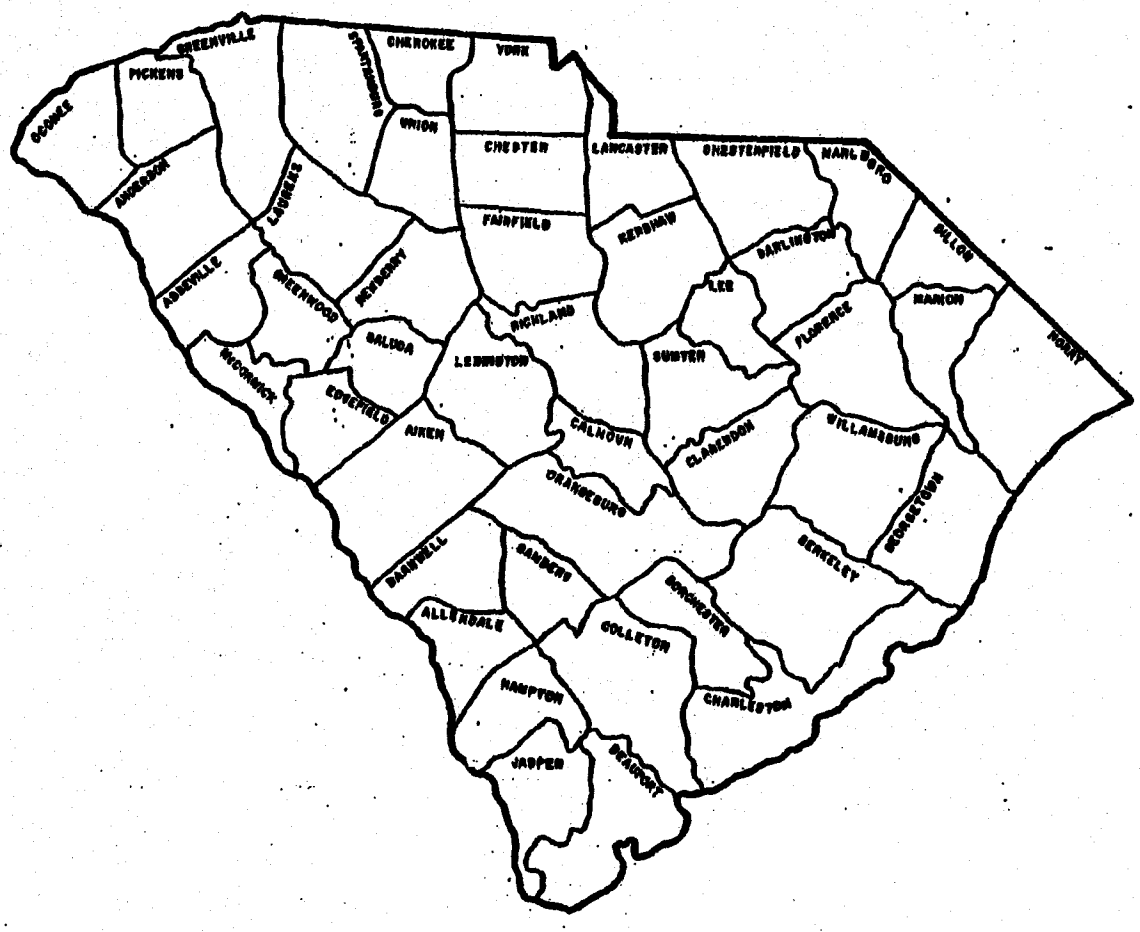
Sincerely,

Mike Biediger/AA

Michael J. Biediger
President & CEO

cc: Mr. Les Shelton, Senior Planner

DRAFT
2007
South Carolina Health Plan



South Carolina State Health Planning Committee

South Carolina Department of Health and Environmental Control

Certificate of Need Standards for Open Heart Surgery

Definitions

"Capacity" means the number of open heart surgery procedures that can be accommodated in an open heart surgery unit in one year.

"Open Heart Surgery" refers to an operation performed on the heart or intrathoracic great vessels. It is identified by the following ICD-9-CM procedure codes: 35.10-35.14, 35.20-35.28; 35.31-35.35, 35.39, 35.41-35.42, 35.50-35.51, 35.53-35.54, 35.60-35.63, 35.70-35.73, 35.81-35.84, 35.91-35.95, 35.98-35.99, 36.03, 36.09, 36.10-36.16, 36.19, 36.2, 36.91, 36.99, 37.10-37.11; 37.32-37.33.

An "Open Heart Surgery Unit" is an operating room or suite of rooms equipped and staffed to perform open heart surgery procedures; such designation does not preclude its use for other related surgeries, such as vascular surgical procedures. A hospital with an open heart surgery program may have one or more open heart surgery units.

"Open Heart Surgical Procedure" means an operation performed on the heart or intrathoracic great vessels within an open heart surgical unit. All activities performed during one clinical session shall be considered one procedure.

"Open Heart Surgical Program" means the combination of staff, equipment, physical space and support services which is used to perform open heart surgery. Adult open heart surgical programs should have the capacity to perform a full range of procedures, including:

(1) repair/replacement of heart valves
(2) repair of congenital defects
(3) cardiac revascularization
(4) repair/reconstruction of intrathoracic vessels
(5) treatment of cardiac traumas.

In addition, open heart programs must have the ability to implement and apply circulatory assist devices such as intra-aortic balloon and prolonged cardiopulmonary partial bypass.

Standards

The standards for open heart surgery in South Carolina are as follows:

(1) The establishment or addition of an open heart surgery unit requires Certificate of Need review, as this is considered a substantial expansion of a health service.

(2) Comprehensive cardiac catheterization laboratories shall only be located in hospitals that provide open heart surgery. The lack of a formal cardiac surgical program within the institution is considered to be an absolute contraindication for therapeutic catheterizations, due to the risk of arterial damage and subsequent need for emergency bypass surgery.

(3) The capacity of an open heart surgery program is determined to be 500 open heart procedures per year for the initial open heart surgery unit and each additional dedicated open heart surgery unit (i.e. each operating room equipped and staffed to perform open heart surgery has a maximum capacity of 500 procedures annually).

(4) There should be a minimum of 200 adult open heart surgery procedures performed annually per open heart surgery unit, within three years after initiation in any institution in which open heart surgery is performed for adults. In institutions performing pediatric open heart surgery there should be a minimum of 100 pediatric heart operations per open heart surgery unit; at least 75 should be open heart surgery.

(5) New open heart surgery services shall be approved only if the following conditions are met:

A. Each existing unit in the service area (defined as all facilities within 60 minutes one way automobile travel, excluding any facilities located in either North Carolina or Georgia) is performing an annual minimum of 350 open heart surgery procedures per open heart surgery program for adult services (70 percent of functional capacity). The standard for pediatric open heart cases in pediatric services is 130 procedures per program.

B. An applicant must project that the proposed service will perform a minimum of 200 adult open heart surgery procedures annually per open heart surgery program, within three years after initiation (the standard for pediatric open heart surgery shall be 100 procedures annually per open heart surgery program within three years after initiation):

1. using a standard of every four (4) diagnostic cardiac catheterizations performed generating one (1) open heart surgery, the applicant must demonstrate that the facility performs sufficient diagnostic cardiac catheterizations to generate the minimum volume of open heart surgeries.

2. the applicant shall provide epidemiological evidence of the incidence and prevalence of conditions for which open heart surgery is appropriate within the proposed service area, to include the number of potential candidates for these procedures;

3. the applicant shall provide an explanation of how the applicant projects the utilization of the service and the effect of its projected utilization on other open heart surgery services, including:

a. the number of patients of the applicant hospital who were referred to other open heart surgery services in the preceding 3 years and the number of these patients who could have been served by the proposed service;

b. the number of additional patients, if any, who will be generated through changes in referral patterns, recruitment of specific physicians, or other changes in circumstances. The applicant shall document the services, if any, from which these patients will be drawn; and

c. the existing and projected patient origin information and referral patterns for each open heart surgery service serving patients from the area proposed to be served shall be provided.

C. No new open heart surgery programs shall be approved if the new program will cause the annual caseload of other programs within the proposed service area to drop below 350 adult procedures or 130 pediatric procedures per open heart surgery program.

(6) Notwithstanding the foregoing and notwithstanding any other standard contained in this Plan, an applicant shall be deemed to have demonstrated that need exists and that improved accessibility outweighs the adverse effects of duplication if the applicant demonstrates compliance with the following four criteria:

A. There are no other open heart surgery programs located in the same county as the applicant; and

B. The proposed facility currently offers cardiac catheterization services and provided a minimum of 1,200 diagnostic catheterizations equivalents, without regard to patient origin, in the previous year of operation; and

C. The applicant currently has more than 300 licensed general acute care hospital beds; and

D. The applicant had more than 65,000 emergency room visits in the previous year of operation.

(7) Expansion of an existing open heart surgery service shall only be approved if the service has operated at a minimum use rate of 70 percent of capacity for each of the past two years and can project a minimum of 200 procedures per year in the new open heart surgery unit. The applicant shall document the other service providers, if any, from which these additional patients will be drawn.

(8) The application shall include standards adopted or to be adopted by the service, consistent with current medical practice as published by clinical professional organizations, such as the American College of Cardiology or the American Heart Association, defining high-risk procedures and patients who, because of their conditions, are at high risk and shall state whether high-risk cases are or will be performed or high-risk patients will be served.

(9) Open heart surgery services should be staffed by a minimum of two physicians licensed by the State of South Carolina who possess the qualifications specified by the governing body of the facility. Protocols should be established that govern initial and continuing granting of clinical staff privileges to physicians to perform open heart surgery and therapeutic cardiac catheterizations. In addition, standards should be established to assure that each physician using the service will be involved in adequate numbers of applicable types of open heart surgery and therapeutic cardiac catheterizations to maintain proficiency.

(10) The open heart surgery service will have the capability for emergency coronary artery surgery, including:

A. sufficient personnel and facilities available to conduct the coronary artery surgery on an immediate, emergency basis, 24 hours a day, 7 days a week;

B. location of the cardiac catheterization laboratory(ies) in which therapeutic catheterizations will be performed near the open heart surgery operating rooms; and

C. a predetermined protocol adopted by the cardiac catheterization service governing the provision of PTCA and other therapeutic or high-risk cardiac catheterization procedures or the catheterization of patients at high risk and defining the plans for the patients' emergency care. These high-risk procedures should only be performed with open heart surgery backup. The cardiac team must be promptly available and capable of successfully operating on unstable acute ischemic patients in an emergency setting.

Scope of Services

Within the hospital, a range of non-invasive cardiac and circulatory diagnostic services, including the following, should be available:

(1) services for hematology and coagulation disorders;
(2) electrocardiography, including exercise stress testing;
(3) diagnostic radiology;
(4) clinical pathology services which include blood chemistry and blood gas analysis;
(5) nuclear medicine services which include nuclear cardiology;
(6) echocardiography;
(7) pulmonary function testing;
(8) microbiology studies;
(9) Coronary Care Units (CCU's);
(10) medical telemetry/progressive care; and
(11) perfusion.

Backup physician personnel in the following specialties should be available in emergency situations:

(1) Cardiology;
(2) Anesthesiology;

(3) Pathology;
(4) Thoracic Surgery; and
(5) Radiology.

Each applicant shall document plans for providing cardiac rehabilitation services to its patients, or plans for establishing referral agreements with facilities offering cardiac rehabilitation services.

Adult open heart surgery services should be available within 60 minutes one way automobile travel for 90% of the population. A pediatric cardiac surgical service should provide services for a minimum service area population with 30,000 live births, or roughly 2 million people. Open heart surgery for elective procedures should be available at least 40 hours per week, and elective open heart surgery should be accessible with a waiting time of no more than two weeks.

All facilities providing open heart surgery must conform with local, state, and federal regulatory requirements, and should meet the full accreditation standards for the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), if the facility is JCAHO accredited.

Relative Importance of Project Review Criteria

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

a. Compliance with the Need Outlined in this Section of the Plan;
b. Community Need Documentation;
c. Distribution (Accessibility);
d. Projected Revenues;
e. Projected Expenses;
f. Ability of the Applicant to Complete the Project;
g. Financial Feasibility;
h. Cost Containment;
i. Staff Resources; and
j. Adverse Effects on Other Facilities.

The Department makes the following findings:

(1) Open heart surgery services are available within sixty (60) minutes travel time for the majority of residents of South Carolina;

(2) Based upon the standards cited above, most of the open heart surgery providers are currently utilizing less than the functional capability (i.e. 70% of maximum capacity) of their existing surgical suites;

(3) The preponderance of the literature on the subject indicates that a minimum number of procedures is recommended per year in order to develop and maintain physician and staff

competency in performing these procedures; and

(4) Increasing geographic access may create lower volumes in existing programs causing a potential reduction in quality and efficiency, exacerbate existing problems regarding the availability of nursing staff and other personnel, and not necessarily reduce waiting time since other factors (such as the referring physician's preference) would still need to be addressed.

(5) Research has shown a positive relationship between the volume of open heart surgeries performed annually at a facility and patient outcomes. As components of the Certificate of Need program, the Department is charged with guiding the establishment of health facilities and services that will best serve public needs and ensure that high quality services are provided in health facilities in this State.

Thus, the Department establishes minimum standards that must be met by a hospital in order to provide open heart surgery. Specifically, a hospital is required to project a minimum of 200 open heart surgeries annually within three years of initiation of services. This is considered to be the minimum caseload required to operate a program that maintains the skill and efficiency of hospital staff and reflect an efficient use of an expensive resource. It is in the public's interest that facilities achieve their projected volumes.

(6) The State Health Planning Committee recognizes the important correlation between volume and proficiency. The Committee further recognizes that the number of open heart surgery cases is decreasing and that maintaining volume in programs is very important to the provision of quality care to the community.

The benefits of improved accessibility will not outweigh the adverse affects of duplication in evaluating Certificate of Need applications for this service.

#17
Richard Baehr – Richard A. Baehr & Associates, Chicago

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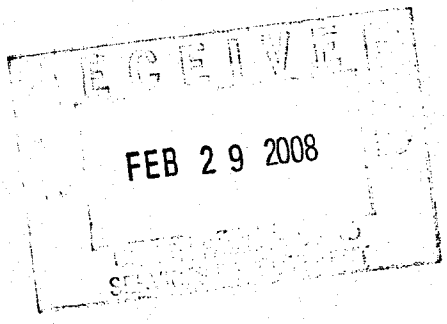

February 28, 2008

Via Hand Delivery
Gerald A. Wilson, M.D.
Chairman
South Carolina Health Planning Committee
Division of Planning and Certification of Need
1777 St. Julian Place, Suite 201
Columbia, South Carolina 29201

Dear Dr. Wilson:

As the Department of Health and Environmental Control approaches the development of the 2008 State Health Plan, we would recommend the Department consider revisions to the section of the plan relating to "Open Heart Surgery." The 2004-2005 State Health Plan is currently in effect. The standards in this section related to open heart surgery have remained fundamentally unchanged from 1993 to the present plan despite significant advancements in clinical research, clinical treatment, and technology in the treatment of cardiac disease, as well as growth in the utilization of these services across South Carolina.

Among the significant changes that have occurred in cardiac care since 1993 are:

- There has been a significant body of research indicating that the most effective treatment for patients presenting at a hospital emergency room with an acute myocardial infarction (or heart attack) is percutaneous coronary intervention (PCI), which is sometimes referred to as angioplasty, or a therapeutic catheterization. Previously, the accepted practice was for patients presenting with a heart attack to receive clot-busting, thrombolytic drugs and then be evaluated for further interventions such as PCI or open heart surgery.

- The research also suggests that PCI is most effective for heart attack victims when delivered within 90 minutes of arrival at the emergency department. The current South Carolina State Health Plan standards limit the performance of PCI, except under tightly defined emergency situations, only to hospitals with on-site open heart surgery backup. Hence, this life-saving treatment may not be available in all cases when patients present to hospital emergency rooms.[1] [2]

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[1] Hannan, Edward L., et al., "Long-Term Outcomes of Coronary-Artery Bypass Grafting versus Stent Implantation," *New England Journal of Medicine*, Vol. May 26, 2005

[2] Serruys, Patrick W., et al., "Five-Year Outcomes After Coronary Stenting Versus Bypass Surgery for the Treatment of Multivessel Disease," Journal of the American College of Cardiology, Vol. 46, No. 4, 2005

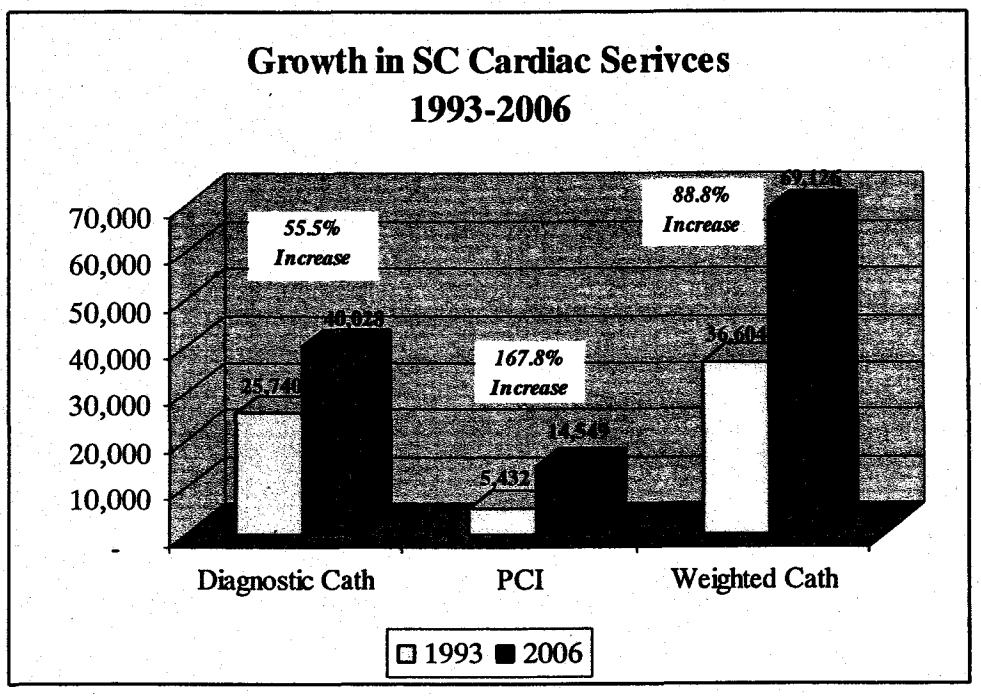
- A number of states permit the performance of PCI without open heart surgery back-up, either through the elimination of CON regulations or entering into a pilot program known as "C-PORT", which is collecting data on the outcomes from programs performing PCI without open heart surgery.

- Recent research findings have contradicted long-held beliefs about the relationship between the volume of open heart surgery cases or PCI cases performed and quality of outcomes experienced by patients. These studies have found that volume is not a strong predictor of outcomes since many programs with relatively low volumes have excellent outcomes and some high volume programs have poor outcomes. Factors such as physician proficiency and quality of the clinical staff at the hospital influence outcomes to a greater extent.

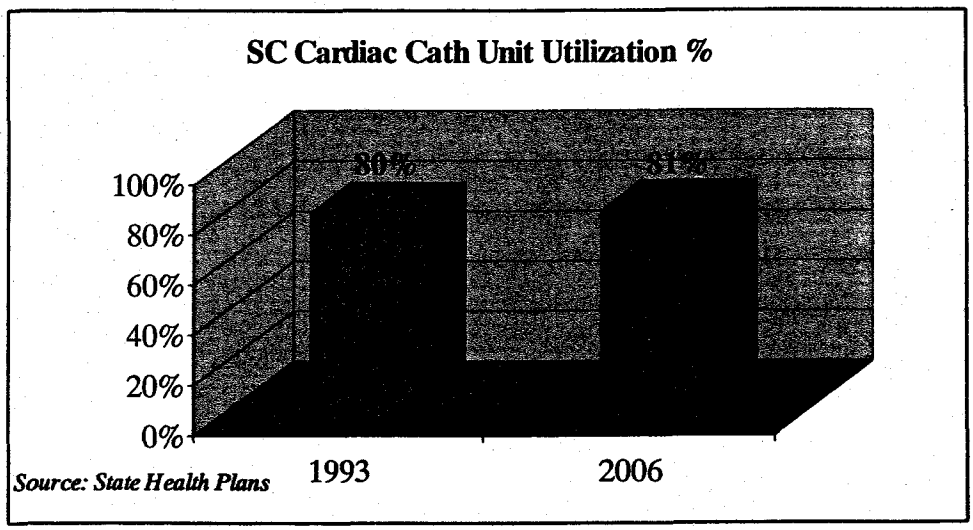
-
    - An important study conducted by Eric Peterson, et al.[3] examined 267,089 coronary artery bypass (CABG) surgeries at 439 U.S. hospitals performed in 2001. The conclusion of their analysis was: "In contemporary practice, hospital procedural volume is only modestly associated with CABG outcomes and therefore may not be an adequate quality metric for CABG surgery."

South Carolina has seen significant changes in the utilization of cardiac services over this period. As shown in the following chart, both diagnostic catheterizations and PCI's have been increasing, with dramatically higher growth in PCI. These trends indicate the increasing importance of PCI as an interventional treatment for cardiac disease. The number of "Weighted Catheterizations," which is calculated based on a weight of 1.0 for diagnostic catheterizations and 2.0 for PCI's, has increased by nearly 90% over the period, indicating that there has been tremendous growth in the need for cardiac catheterization capacity.

[3] Peterson, Eric D., et al., "Procedural Volume as a Marker of Quality for CABG Surgery," Journal of the American Medical Association, Vol. 291, No. 2, January 14, 2004



The number of fixed cardiac catheterization units has grown from 38 to 71 between 1993 and 2006, but the demand for capacity has kept pace. As shown in the following chart, despite the near doubling of cardiac catheterization units in the state, the overall utilization percentage has increased slightly to 81%. There is no excess capacity in cath labs generally throughout the state.



Open heart surgery services have also seen growth over the period from 1993 to 2006. In 1993, 3,825 open heart surgeries were performed in South Carolina, and by 2006, the number had grown to 5,438, a 42.2% increase. Open heart volumes have declined somewhat in recent years given that certain patients previously receiving open heart surgery now are treated with PCI. The total number of patients receiving interventional treatment (open heart surgeries plus PCIs), however, has increased steadily over the period from 9,257 in 1993 to 19,987 in 2006, a rise of 115.9%. Clearly the need for cardiac intervention continues to grow.

Given these findings and practice trends, there are a number of changes that should be made in the 2008 South Carolina State Health Plan to ensure appropriate access to interventional cardiac services such as PCI and open heart surgery.

Proposed Changes to Open Heart Surgery Standards

1. ***Change the basis for determining capacity from an open heart surgery unit to a program.***

The State Health Plan has consistently utilized an open heart unit, which is defined as a dedicated open heart surgery operating room, to determine the utilization and capacity of an open heart program. The current standards do not permit the approval of new open heart surgery programs if the approval would cause the annual caseload of other open heart programs in the proposed service area to fall below 350 adult open heart surgery procedures per open heart surgery unit. There are a number of problems with the use of "units" to make this determination:

- There is an underlying assumption that an open heart surgery operating room is used only for open heart surgeries. It is common practice for hospitals to perform vascular, thoracic, and other procedures in these rooms, yet DHEC gives no consideration to these other procedures in measuring the extent of utilization.

- A principal concern expressed by DHEC in these standards is that volumes of open heart surgeries will fall at existing providers if new providers enter the market, and that these volume declines would result in poor outcomes or inefficiencies. There are no studies that have measured quality in open heart programs based on volume of procedures per operating room. All of the studies relate to volumes per program. With one exception, other states in the Southeast that maintain CON programs regulate the number of programs, not units. There is no logical basis for considering capacity based on the number of open heart operating rooms.

2. ***Eliminate the statement in the State Health Plan indicating: "The benefits of improved accessibility will not outweigh the adverse effects of duplication in evaluating Certificate of Need applications for this service." Improved access should be at the top of the list of CON criteria.***

   - Given the significant increase in the demand for interventional cardiac services, accessibility is a critical, and in some cases a life-or-death, consideration. Access to care should not take a back seat to protecting the revenue streams of existing providers.

   - Each CON review requires a careful balancing of CON criteria. Indeed, the current open heart surgery standards list 10 different criteria that are applicable to the review of open heart surgery programs. However, DHEC allows one criterion, "Adverse Effects on Other Facilities," to trump all other considerations. The impact of DHEC's current position is that the remainder of the State Health Plan standards are rendered meaningless.

   - A clear example of DHEC's disproportionate weighting of "adverse effects on other facilities" resulting from current application of the standards relates to the single county exception to the need provisions for hospitals applying for a new open heart surgery program. The current standards allow for an exception for hospitals that are located in counties with no open heart surgery program if the applicant hospital has performed a minimum of 1,200 diagnostic catheterization equivalents in the previous two years. Lexington Medical Center applied for a CON in 2004 and met this exception, yet DHEC denied the application given concerns about impact on existing providers. DHEC granted this exception to Anderson Area Medical Center in 2001, and that program has achieved and maintained significant volume, performing 265 open heart surgeries in 2006.

   - As discussed above, a major factor driving DHEC's current position is a belief that the volume and the quality of open heart surgery programs is directly related. The most recent clinical research demonstrates that volume is not a good predictor of outcomes. The current standards work in two ways to limit the ability of new applicants to obtain approval for a new open heart program by adhering to this old, and no longer accepted relationship- by assuming that any loss of volume by existing providers will result in a decline in quality at these programs, and by assuming that new programs will not have enough volume to achieve a quality program.

3. ***Change the current requirement in the State Health Plan that each existing adult open heart unit in the service area is performing a minimum of 350 open heart surgery procedures to a requirement that each existing open heart surgery program in the service area is performing a minimum of 200 open heart surgery procedures. Modify any adverse impact test such that new applicants for open heart surgery programs will not drive existing providers below a level of 200 procedures per year.***

   - The research on the relationship between volume of procedures and outcomes does not establish any minimum volume required to achieve quality.

   - There are a number of programs in South Carolina today that perform fewer than 350 open heart surgeries annually that produce quality outcomes.

   - Given that open heart surgery backup is required to perform PCI for all patients, and the number of such patients requiring either open heart surgery or PCI is increasing, ensuring access to care is more important than adhering to arbitrary volume targets.

Incorporating these changes in the new State Health Plan will make it more likely that access to interventional cardiology services will improve, and will enable the State Health Plan to reflect the most current research on interventional cardiology services.

Thank you for your consideration of these comments.

Very truly yours,

Richard A. Baehr & Associates

cc: Mr. Les Shelton (*via hand delivery*)

#18
Douglas Bryant – The Bryant Company

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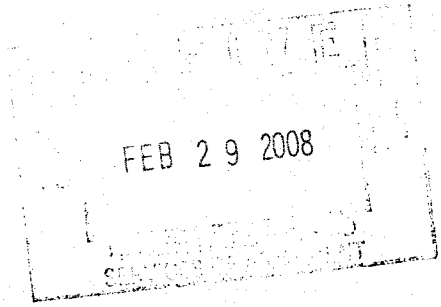
February 29 2008



Mr. Les Shelton
Director of Planning and CON
DHEC
2600 Bull Street
Columbia, SC 29201

Dear Mr. Shelton: Les

Attached please find a copy of the remarks made by Mr. Phillip Wright during the Public Hearing concerning the 2008-2009 draft State Health Plan. Please consider these comments on behalf of Mary Black Hospital.

Also attached are the following:

- the requested amendment to Section II-45
- a copy of the article from the *Society for Cardiovascular Angiography and Interventions;*
- the February 28, 2008 letter from Dr. Thomas Aversano; and
- a copy of the Georgia rules concerning adult cardiology and the CPORT study.

Thank you for allowing us to provide these comments and your favorable consideration would be appreciated.

Sincerely,

Douglas E. Bryant

Thank you for the opportunity to speak to you this morning concerning the Draft 2008-2009 State Health Plan.

I want to thank you Mr. Shelton (Les Shelton), and the members of the DHEC staff for your hard work over the last several years in reviewing the data and compiling an excellent plan.

I am especially pleased that you have included a provision for three hospitals to participate in the Johns Hopkins based Atlantic CPORT study.

I believe the study will provide valuable information as we continue to adapt our State's health policies. It was stated by one speaker during the Public Hearing on February 29, 2008 that the CPORT study is not in keeping with the recommendations of the American College of Cardiology. This is a misstatement of the American College of Cardiology's position as Dr. Aversano, the Chief Investigator for the CPORT study, stated during the Public Hearings on the State Health Plan last year "the American College of Cardiology recommends PCI only in facilities with on-site open heart surgery until further data is available." Studies such as CPORT are designed specifically to obtain the data the American College of Cardiology requires.

One of the speakers also mistakenly stated that there were only 2000 participants in the CPORT study. There are currently 6000 participants in the CPORT study.

I have two recommended changes to the plan both are in the Section on open heart surgery starting on page II-45 concerning the conditions for participation in the CPORT study.

On page II-45 (9) A and B

(9)(A) requires that a hospital be at least thirty minutes, one way driving, from a hospital with open heart surgery in order to participate in the CPORT study.

This is an unnecessary restriction. In other states, such as Georgia, the ten hospitals selected to participate in the CPORT study were selected from a mix of rural and urban facilities (see attached copy of Georgia Rule 111-2-2 (f) 3(ii)). The requirement is also counter to the argument that has been made by those who are opposed to the CPORT study being approved for South Carolina. If we are to take into consideration their concerns that these procedures should be conducted only in hospitals with on-site open heart surgery, it would seem that having the trial program conducted closer to a hospital with on-site open heart surgery would be appropriate until the end of the three year study period.

(9) (B) as a condition to participate in the CPORT study a hospital must be approved or apply for a CON to provide emergency (primary) percutaneous coronary intervention (PCI).

I believe this condition to be an unnecessary burden for those who desire to apply for participation in the CPORT study.

The plan requires a CON for participation in CPORT which I support. In order to be accepted as a CPORT participant, a hospital must meet or surpass all of the rigorous standards established by the Johns Hopkins' sponsored program. The protocol that I know the staff has reviewed is

stringent and medically sound. The CPORT selection process, training requirements, and practice protocols are backed by the expertise of Johns Hopkins and sufficient to provide for patient care and safety. An additional CON is duplicative and unneeded.

If the requirement for an emergency CON is not eliminated, I request that the number of procedures required to qualify for primary or emergency PCI be reduced to 300 for the first year and increased to up to 500 procedures within three years.

As is pointed out in Dr. Aversano's letter of February 28, 2008, all States participating in CPORT to date perform a minimum of 100 PCI in their first year and ramp up to 200 in the second year. The current requirement in the draft State Health Plan is a minimum of 600 diagnostic procedures in order to qualify for emergency PCI. This requirement makes it exceedingly difficult for facilities to qualify for the CPORT study. As can be determined by reading the letter from Dr. Aversano, this requirement is excessive and should be reduced to 300.

Currently between approximately one dozen States including our neighboring States of Georgia and North Carolina allow hospitals to participate in CPORT. According to a 2007 publication of the Society of Cardiovascular Angiography and Interventions, twenty eight (28) states have facilities performing both primary and elective PCI without on-site open heart surgery. One of the article's recommendations includes the following statement: "PCI without on-site surgical backup is being performed with acceptable outcomes and risks in the US and many other countries. The recommendations outlined in this document are made to ensure patient safety and quality outcomes in such a work environment."

The article further states that "over the past 20 years, the use and indications for PCI have greatly expanded. It is now well-recognized that PCI is safer and the need for urgent coronary artery bypass graft (CABG) surgery greatly reduced primary PCI, when available . . . ."

I recommend that the DHEC staff review the findings of States such as Georgia, and amend the State Health Plan by omitting Section II-45 (9) and inserting the attached amendment.

Again thank you for the opportunity to speak and I look forward to working with you.

Phillip L. Wright, CEO

Mary Black Health Systems, LLC

February 29, 2008

(Amendment to Draft State Health Plan 2008-2009, Page II-45 item 9 strike and insert the following)

The Department staff may approve applications to perform Percutaneous Coronary Intervention (PCI) in hospitals without on-site cardiac surgery for the purpose of participation in medical research. Applicants approved for such research studies must be participants in the Atlantic Cardiovascular-Patient Outcomes Research Team study (CPORT) and shall meet all of standards outlined in the most current CPORT operations manual/protocol. If a hospital fails to receive approval from the Department for this service or if the hospital is expelled or otherwise loses the approval to participate the Department's approval will be simultaneously withdrawn without the hospital having the right to an appeal.

Research studies approved by the Department for this purpose shall be determined by utilizing the most current data available and not limited to the data listed in the 2008-2009 State Health Plan. Performance of PCI at participating sites is permissible only for the duration of the study and only for patients who consent to participate. Under no circumstances shall the project be approved for more than three (3) years from the date of the first procedure. A maximum of three (3) hospitals may be approved for participation in the research study.

Approval of such research shall not be construed to be permission or approval for any other activity than the participation in a specific medical research study.

Catheterization and Cardiovascular Interventions 69:000–000 (2007)

Executive Summary

The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions

Gregory J. Dehmer,[1]* MD, James Blankenship,[2] MD, Thomas P. Wharton Jr.,[3] MD, Ashok Seth,[4] MD, MBBS, DSc, Douglass A. Morrison,[5] MD, PhD, Carlo DiMario,[6] MD, David Muller,[7] MD, Mirle Kellett,[8] MD, and Barry F. Uretsky,[9] MD

*The full-length version of this article can be found on the **Catheterization and Cardiovascular Interventions** website (http://www.mrw.interscience.wiley.com/suppmat/1522-1946/suppmat/index.html) and on the SCAI website at www.scai.org.*

PREAMBLE

The Society for Cardiovascular Angiography and Interventions (SCAI) coauthored and cosponsored with the American College of Cardiology (ACC) and the American Heart Association (AHA) the percutaneous coronary intervention (PCI) guidelines update, released in November 2005 [1]. This guideline update continued to designate elective PCI without on-site surgery as a Class III indication, and primary PCI for ST-segment elevation myocardial infarction (STEMI) as a class IIb indication in the absence of on-site surgery. The performance of PCI without on-site surgical backup is currently the subject of debate. Although providing the highest quality of care and best outcomes to patients should always be the primary goal, debate on this topic has the potential to supersede quality of patient care issues. Within this context, SCAI developed this Expert Consensus document to determine the current status of PCI without on-site surgery not only in the United States, but globally, and make recommendations regarding the performance of PCI in this circumstance. The focus of this document is to provide a structure that provides the highest quality care to patients undergoing PCI in any circumstance.

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[7]St. Vincent's Hospital, Melbourne, Australia
[8]Maine Medical Center, Portland, Maine
[9]Sparks Health System, Fort Smith, Arkansas
See Appendix Table

Endorsed by the following societies: Asian Pacific Society of Interventional Cardiology, Belgian Working Group of Interventional Cardiology, Brazilian Society for Interventional Cardiology, British Cardiovascular Intervention Society, Working Group on Interventional Cardiology of the Bulgarian Cardiology Society, Cardiac Society of Australia and New Zealand, Egyptian Society of Cardiology Working Group on Interventional Cardiology, Interventional Council of the Cardiological Society of India, Italian Society of Interventional Cardiology, Working Group on Interventional Cardiology of the Latvian Society of Cardiology, Polish Working Group on Interventional Cardiology of the Polish Cardiology Society, Sociedad Venezolana de Cardiología Intervencionista (Venezuelan Society of Interventional Cardiology).

*Correspondence to: Gregory J. Dehmer, MD, FSCAI, Professor of Medicine, Texas A&M School of Medicine, Director, Cardiology Division, Scott & White Clinic, 2401 South 31st Street, Temple, Texas 76508. E-mail: president@scai.org

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WILEY InterScience DISCOVER SOMETHING GREAT

BACKGROUND

Over the past 20 years, the use and indications for PCI have greatly expanded. It is now well-recognized that PCI is safer and the need for urgent coronary artery bypass graft (CABG) surgery greatly reduced [2]. Primary PCI, when available, has eclipsed fibrinolytic therapy for reperfusion in the treatment of STEMI [3], but is adversely affected by time delays in initiating the PCI procedure [4]. Studies examining patient transport to PCI hospitals have shown suboptimal initial door-to-balloon times, especially in the United States [5]. Efforts to provide primary PCI services locally at community hospitals without on-site cardiac surgery have developed and demonstrate outcomes comparable to facilities that have on-site cardiac surgery [6]. Because it is difficult to sustain a PCI program solely on STEMI patients, elective PCIs are also being performed at facilities without on-site surgery [7], enhancing the debate regarding PCI without on-site surgery.

PREVALENCE AND TRENDS OF PCI WITHOUT ON-SITE SURGERY

Data on the prevalence of PCI performed without on-site surgical backup in the United States are not easily found and are changing rapidly. Data gathered from several sources and believed accurate as of July 2006 indicate primary PCI programs without on-site surgical backup exist in all but 10 states (Alaska, Arkansas, Delaware, Georgia, Mississippi, North Dakota, Rhode Island, South Dakota, Vermont, and Wyoming) plus the District of Columbia. Facilities performing both primary and elective PCI without on-site surgery currently exist in 28 states. A large (n = 18,000) randomized trial of elective PCI without on-site surgery (The Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study) is currently enrolling patients and includes facilities in several states where elective PCI without on-site backup has been prohibited.

The exact number of patients receiving PCI at facilities without on-site surgery is unknown. Data from facilities reporting to the CathPCI Registry™ of the ACC-National Cardiovascular Data Registry (ACC-NCDR®) show an increase in the number of both primary and elective PCIs performed without on-site surgical backup [8]. In 2005, 75 of the 463 facilities reporting to the ACC-NCDR were performing PCI without on-site surgical backup.

PCI without on-site surgical backup is being performed in 35 of 39 (90%) countries responding to requests for information and appears to be increasing. For example, 7% of PCI procedures performed in the United Kingdom in 1996 were at facilities without on-site cardiac surgery. By 2004, this increased to 15% with 26% of the PCI centers in the United Kingdom operating without on-site cardiac surgery.

EXISTING GUIDELINES AND COMPETENCY DOCUMENTS

ACC/AHA/SCAI Guidelines

In the 2005 update of this guideline, primary PCI without on-site surgical backup remained a Class IIb indication, and elective PCI without on-site surgery remained a Class III indication. Many other programmatic recommendations were made [1].

European Society of Cardiology Guidelines

In contrast to the ACC/AHA/SCAI guidelines, the 2005 European Society of Cardiology (ESC) guidelines do not comment on PCI without on-site cardiac surgery or issues related to institutional or operator competency [9].

British Cardiac Society and British Cardiovascular Intervention Society Guidelines

The British Cardiac Society and British Cardiovascular Intervention Society (BCIS) guideline, published in 2005, acknowledges and approves PCI without on-site surgical backup and emphasizes a common standard applied across facilities with and without on-site surgical backup so as to avoid two levels of service provision [10].

German Guidelines

The only German guidelines found were published in 1987 [11] and thus may not be relevant today. However, there is substantial evidence that PCI without on-site surgical backup is widely performed in Germany.

The Cardiac Society of Australia and New Zealand Guidelines

Policy statements on support facilities and on the performance of coronary angiography and PCI at rural sites in Australia and New Zealand were published (online) in 2003 and 2005, respectively [12,13]. The Cardiac Society of Australia and New Zealand (CSANZ) guidelines state that PCI is preferably performed in hospitals with on-site surgical support, but acknowledge that the requirements for on-site cardiac surgical facilities may be omitted in certain circumstances, and that appropriately trained individuals can perform coronary interventional procedures safely in hospitals without on-site surgical

backup. Furthermore, these documents acknowledge that rural patients have reduced access to diagnostic angiography and interventional procedures and further state that providing these services as close to the patient's place of residence as possible facilitates equity of access, which should result in improved quality of care.

Spanish Society of Cardiology Guidelines

Published in 1999 [14], these guidelines are specific for PCI at hospitals without on-site cardiac surgery. PCI performance without on-site cardiac surgery is not prohibited, provided a program meets certain requirements.

Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista

Guidelines from the Brazilian Society of Cardiac Hemodynamics and Intervention (Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista) [15] were published in 2003. They use a scheme similar to the ACC/AHA/SCAI guidelines [1] and classify elective PCI without on-site surgical backup as Class III. Primary PCI for STEMI in the absence of on-site surgery is a Class IIa indication; their guidelines do not have a IIb category.

Belgian Working Group on Invasive Cardiology Guidelines

Published in 2003, these guidelines acknowledge the increasing safety and diminishing risk of PCI but conclude that "the current standard practice for elective PCI remains the presence of on-site surgical standby" [16].

PEER-REVIEWED LITERATURE OF PCI WITHOUT ON-SITE SURGERY

There are over 30 published papers or abstracts reporting PCI results without on-site surgical backup. All published data for both primary and elective PCI were derived from retrospective reviews or registries, and thus are subject to unintentional bias and other methodological concerns. These are summarized and referenced in the on-line version of this document. These studies span a time period from 1990 to 2006, and thus incorporate changing treatment paradigms, including fibrinolytic therapy before PCI, glycoprotein IIb/IIIa inhibitors, and coronary artery stents. The total patient number within some of these reports is not easily derived because the studies listed are expanding experiences within the same registry; thus, simple aggregation of outcome data is not appropriate or meaningful. The more recent reports show that both primary and elective PCI without on-site surgical backup are performed with a high success rate, low in-hospital mortality rate, and a low rate of urgent cardiac surgery.

BEST PRACTICES FOR PCI WITHOUT ON-SITE SURGERY

Although no randomized or controlled studies exist and despite the current ACC/AHA/SCAI guideline recommendation, PCI without on-site surgery is being performed in many states and is accepted in many countries throughout the world. Moreover, data from many countries, including the United States, indicate that the use of PCI without on-site surgery is growing [8]. The purpose of this document is neither to challenge the ACC/AHA/SCAI guideline recommendations nor to support PCI without on-site surgery backup. However, with the reality that PCI without on-site surgery is growing, it is both appropriate and necessary to define the best standards of practice such that facilities and physicians operate within the highest possible quality standards.

Qualifications of the Physician

Simply performing a high volume of cases does not guarantee technical expertise or sound judgment on the part of the physician. More important than a specific case volume threshold is the accurate assessment of complication rates and patient outcomes. Recommendations for physicians performing PCI at facilities without on-site surgery include the following:

a. Only operators with complication rates and outcomes equivalent or superior to national benchmarks should perform PCI procedures with or without on-site surgery. The operator also must actively participate in a facility's quality improvement program. In addition to involvement in local continuous quality improvement efforts, participation in a national data registry if available and appropriate continuing medical education is mandatory.
b. A proven record of satisfactory outcomes is of greater importance than simply meeting an arbitrary case volume requirement. However, operators must have sufficient prior experience to allow assessment of their judgment and quality. The initial operators at a facility without on-site backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Interventional cardiologists joining those already engaged in PCI without on-site surgery with <500 cases of lifetime experience should be mentored and monitored by existing physicians until it is determined and certi-

TABLE I. Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup

Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.
On-call schedule with operation of laboratory 24 hr/day, 365 days/year[a].
Experienced coronary care unit nursing staff, comfortable with invasive hemodynamic monitoring, temporary pacemaker operation, and intraaortic balloon pump management. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (e.g., respiratory care, blood bank, etc.).
Written agreements for the emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of twice per year.
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and intraaortic balloon pump equipment compatible with transport vehicles. The ability for the real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is ideal.
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes, thrombectomy and distal protection devices, covered stents, temporary pacemakers, pericardiocentesis trays. Pressure wire device and intravascular ultrasound equipment are optimal but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities due to the greater risk of perforation.
Meticulous clinical and angiographic selection criteria for PCI (Tables II and III).
Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked and be ≤90 min. Outlier cases should be carefully reviewed for process improvement opportunities.
On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.
Participation in a national data registry where available, such as the American College of Cardiology-National Cardiovascular Data Registry[tm] in the United States.

CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation acute myocardial infarction.
[a]Required for the United States facilities, but this may not be possible for all facilities world-wide.
Adapted from Ref. 6.

TABLE II. Recommendations for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in:
Patients with >50% stenosis of left main artery proximal to infarct-related lesion especially if the area in jeopardy is relatively small and the overall LV function is not severely impaired.
Long, calcified or severely angulated target lesions at high-risk for PCI failure with TIMI grade 3 flow present during initial diagnostic angiography.
Lesions in other than the infarct artery (unless they appeared to be flow-limiting in patients with hemodynamic instability or ongoing symptoms).
Lesions with TIMI grade 3 flow that are not amenable to stenting in patients with left main or three-vessel disease that will require coronary bypass surgery.
Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention.
Transfer emergently for coronary bypass surgery patients with:
High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with intra-aortic balloon pump support.
Failed or unstable PCI result and ongoing ischemia, with intra-aortic balloon pump support during transfer.

LV, left ventricular; PCI, percutaneous coronary intervention; TIMI, Thrombolysis in Myocardial Infarction.
Adapted from Ref. 6.

fied formally by that hospital that their skills and judgment are excellent and outcomes equivalent or superior to the national benchmarks.

c. Operators performing PCI without on-site surgery should perform ≥100 total PCIs per year, including ≥18 primary PCIs per year. These numbers exceed those currently recommended in the ACC/AHA/SCAI guidelines to reflect the opinion of this writing group that a greater experience level is appropriate for PCI in this setting.

d. In the United States, board certification in interventional cardiology by the American Board of Internal Medicine is strongly recommended for all physicians performing PCI.

Facilities and Support Personnel

It is essential that all support personnel have adequate education regarding the management of PCI patients before, during, and after the procedure. This knowledge should include potential procedural complications and their management and the drug therapies used in PCI patients (Table I).

Facilities performing both primary and elective procedures without on-site surgery should perform a minimum of 200 PCI/year. Programs with <200 PCI/year should be reviewed on an individual basis. They should remain open only if they are in geographically isolated or under-served areas and their performance metrics are equivalent to accepted benchmarks. We recommend that each country or state review this issue, and establish an absolute minimum annual case volume below which a PCI program must close under any circumstance. In the United States, this minimum should be 150 PCI/year for a program offering both primary and elective PCIs and this must include a minimum of 36 primary PCI/year. Programs offering only primary PCIs must perform a minimum of 36 primary PCIs/year to remain operational. At the present time in the United States, there is no justification for a PCI

TABLE III. Recommendations for Patient and Lesion Selection and Backup Strategy for Nonemergent PCI at Hospitals Without On-site Cardiac Surgery and by Operators Performing ≥100 PCIs/Year

Patient Risk: expected clinical risk in case of occlusion caused by procedure.

High Patient Risk: Patients with any of the following:

- decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders;
- left ventricular ejection fraction ≤25%;
- left main stenosis (≥50%) or three-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries);
- single target lesion that jeopardizes over 50% of remaining viable myocardium.

Lesion Risk: probability that procedure will cause acute vessel occlusion.

Increased Lesion Risk: lesions in open vessels with any of the following characteristics:

- diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments;
- more than moderate calcification of a stenosis or proximal segment;
- location in an extremely angulated segment (>90°);
- inability to protect major side branches;
- degenerated older vein grafts with friable lesions;
- substantial thrombus in the vessel or at the lesion site;
- any other feature that may, in the operator's judgment, impede successful stent deployment.
- aggressive measures to open chronic total occlusions are also discouraged due to an increased risk of perforation.

Strategy for Surgical Backup Based on Lesion and Patient Risk:

High-Risk Patient with High-Risk Lesion should not undergo nonemergent PCI at a facility without on-site surgery.

High-Risk Patient with Not High-Risk Lesion: nonemergent patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room is immediately available is necessary.

Not High-Risk Patient with High-Risk Lesion requires no additional precautions.

Not High-Risk Patient with Not High-Risk Lesion requires no additional precautions. Best scenario for PCI without on-site surgery.

CVA, cerebrovascular accident; PCI, percutaneous coronary intervention. Adapted from Ref. 6.

TABLE IV. Requirements for Off-Site Surgical Backup

1. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility.
2. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.
3. Cardiac surgeons and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours
4. Surgeon and receiving facility assure that patient will be accepted based on medical condition, capacity of surgeons to provide services at the time of request and availability of resources. If this cannot be assured before starting an elective procedure, the case should not be done at that time.
5. Interventional cardiologist must review with the surgeon the immediate needs and status of any patient transferred for urgent surgery.
6. Hospital administrations from both facilities endorse transfer agreement.
7. Transferring and receiving facility establish a rigorous protocol for the rapid transfer of patients, including the proper personnel with appropriate experience.
8. Transport provider is available to begin transport within 20 min of the request and provide vehicle/helicopter with necessary life-sustaining equipment, including IABP and monitoring capability.
9. Transferring physician obtains consent for surgery from patient or appropriate surrogate.
10. Initial informed consent for PCI discloses that procedure is being done without on-site surgical backup and acknowledges possibility of risks related to transfer. The consent process should include the risk of urgent surgery (~0.3%) and state that a written plan for transfer exists.
11. As part of the local continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.

IABP, intraaortic balloon pump; PCI, percutaneous coronary intervention.

program without on-site surgery to perform only elective procedures or not provide availability to primary PCI 24 hr/day, but such a situation may exist in other countries and be appropriate. New programs should have 2 years to reach the absolute minimum volume, but after that programs failing to reach this volume for 2 consecutive years should not remain open under any circumstance.

Patient and Lesion Selection

Rigorous clinical and angiographic selection criteria are essential for programs performing PCI without on-site surgery. Since the clinical situation and risk-to-benefit ratio are different for primary versus elective PCI, different criteria and standards should apply (Table II). In elective PCI without on-site surgery, it is necessary to assess not only the likelihood of PCI failure, but also the potential patient risk if complications occur since it is possible to have a low-risk lesion in a high-risk patient and vice versa. It is important to consider both the patient and lesion risk when developing criteria for selection of appropriate patients for treatment in facilities without on-site surgery (Table III).

Requirements for Off-Site Surgery

A close alliance and cross-communication with cardiovascular surgeons with formalized agreements and periodically tested protocols for the emergency transfer of patients are essential (Table IV). Interventional cardiologists and cardiac surgeons must be actively involved in the program with attendance at regularly scheduled cardiac catheterization conferences and participation in risk management activities.

In hospitals with on-site surgery, it is no longer standard for a surgical suite to be held open awaiting the completion of a PCI. Because the need for urgent

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Cardiovascular Patient Outcomes Research Team

February 28, 2008

Phillip L. Wright, FACHE
Chief Executive Officer
Mary Black Health System LLC
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P.O. Box 3217
Spartanburg, SC 29304

Dear Mr. Wright:

We spoke yesterday regarding diagnostic catheterization volume requirements for C-PORT E participation. As stated in the Manual of Operations for this project, there are no specific diagnostic catheterization laboratory volume requirements for participation in the study. However, there are angioplasty (PCI) volume requirements: participating hospitals must be capable of performing a minimum of 200 PCI's per year. This volume is the sum of primary and non-primary (or elective) PCI volume.

All states participating to date have required that hospitals involved in CPORT-E perform a minimum of 100 PCIs in their first year of participation and then ramp up to 200 in the second year. This is to give new sites a reasonable 'start-up' period. This also acknowledges an obvious fact: many hospitals that currently do not perform PCI have low diagnostic catheterization volume numbers because patients and their physicians "bypass" their cath labs so that they can have both the diagnostic and any potential therapeutic catheterization in a single sitting at a tertiary hospital. As a result, many non-PCI labs have experienced a rather dramatic decline in diagnostic volume over the past several years.

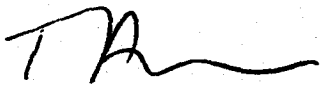
To show that there is the realistic potential for adequate diagnostic volume requires two critical elements (1) the hospital needs to demonstrate the number of patients who could have had catheterization at their laboratory but did not and (2) demonstrate that the physicians referring those patients are committed to re-directing them to that hospital's laboratory. For example, the referring cardiologists certainly know the number of caths (and probably the number of PCIs), generated in their practice from a given hospital catchment area (or even the hospital itself). Simply getting those cardiologists to confirm their intention to refer those patients to the community hospital and documenting an adequate number is a good way to support the idea there is adequate diagnostic volume. There are a number of other methods that can be used to estimate this number, as well.

Regardless, the point is that potential CPORT-E hospitals often have a relatively low initial diagnostic volume. Requiring a higher initial volume clearly excludes most sites. This, in my view, can be unnecessarily restrictive because such hospitals are in a "Catch-22" situation: they can't participate in the PCI demonstration project because they have a low diagnostic cath lab volume and they have a low diagnostic cath lab volume because they don't perform PCI.

Assuming that a hospital has approximately 50 primary PCIs per year and that one needs, therefore, an additional 150 PCIs to sum to 200 per year, and that 30% of diagnostic catheterization patients require PCI, then a diagnostic volume of 500 catheterizations could be sufficient for participation. Obviously, the higher the diagnostic cath lab volume, the more likely it is that 200 PCIs per year can be achieved.

Thank you for your continued interest in the CPORT-E project. Please let me know if I can be of further assistance to you or provide any additional information.

Sincerely yours,



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RULES
OF
DEPARTMENT OF COMMUNITY HEALTH

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111-2
HEALTH PLANNING

111-2-2
Certificate of Need

111-2-2-.21 Specific Review Considerations for Adult Cardiac Catheterization Services. Amended May 8, 2005.

(1) **Applicability.**

(a) For Certificate of Need (CON) purposes, Adult Cardiac Catheterization Services is classified as a specialized service and is defined as a new institutional health service which must be delivered in a permanently fixed location in either an acute care hospital or in a diagnostic, treatment, or rehabilitation center (DTRC). A certificate of need will be required prior to the establishment of a new or expanded adult cardiac catheterization service.

(b) If the services will be provided within a licensed acute care hospital, the hospital shall be the applicant.

(c) If cardiac catheterization services will be provided in a DTRC, the organizational entity that develops the service shall be the applicant.

(d) Seeking and receiving approval from the Department under the provisions of 111-2-2-.21 (3)(f)3 shall neither be considered a new adult cardiac catheterization service nor an expanded service. Additionally, the issuance of such an approval shall not be construed to be anything other than a time-limited approval to participate in the particular medical research trial specified in 111-2-2-.21(3)(f)3.

(2) **Definitions.**

(a) "Adjacent acute care hospital" means an acute care hospital which is physically connected to another acute care hospital in a manner that emergency transport of a

patient by a stretcher or gurney can be achieved rapidly, conveniently, and effectively without the use of motorized vehicles.

(b) "Adult" means a person 15 years of age and over.

(c) "Authorized service" means an adult cardiac catheterization service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not yet become operational.

(d) "Capacity" means 1300 adult cardiac catheterization procedure equivalents per dedicated and multipurpose room per year. In the computation of the use rate (percent of capacity) of authorized adult cardiac catheterization rooms, each adult diagnostic cardiac catheterization and other cardiac catheterizations of similar complexity shall equal a 1.0 procedure equivalent, each coronary angioplasty procedure shall equal 1.5 procedure equivalents, and each electrophysiological (EP) study shall equal 2.0 procedure equivalents. If pediatric catheterizations are performed in a room in which adult cardiac catheterizations are performed, each pediatric procedure shall equal 2.0 procedure equivalents.

(e) "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

(f) "Cardiac catheterization service" means an organized program which serves inpatients and/or outpatients of an acute care hospital or diagnostic, treatment and rehabilitation center (DTRC) with a room or a suite of rooms, with equipment to perform angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization procedures. An authorized adult cardiac catheterization service is prohibited from performing coronary angioplasty procedures unless the acute care hospital where the service is located meets the requirements identified in 111-2-2-.21(3)(f)

(g) "Coronary angioplasty" means a cardiac catheterization procedure to treat coronary artery disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.

(h) "Diagnostic cardiac catheterization" means the performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart, or abnormalities in the heart structure, whether congenital or acquired. Post-operative evaluation of the effectiveness of prostheses (e.g. heart valves or vein grafts) also can be accomplished through use of diagnostic cardiac catheterization.

(i)"Diagnostic, treatment, or rehabilitation center (DTRC)" means any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting that is not part of a hospital.

(j) "Expanded Service" or "Expansion" means an adult cardiac catheterization service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the cardiac catheterization services are or will be offered, the cost of which exceeds the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment threshold at that time which is to be utilized in the provision of cardiac catheterization services; or that seeks the addition of a new catheterization laboratory or room regardless of cost. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such services is not an expansion for purposes of these Rules.

(k) "Horizon year" means the last year of a five-year projection period for need determinations for any adult cardiac catheterization services.

(l) "Official inventory" means the Department's inventory of all authorized hospital-based and diagnostic, treatment, or rehabilitation center (DTRC) adult cardiac catheterization laboratories or any other authorized laboratory approved for operation at the time of adoption of these Rules.

(m) "Official state component plan" means the document related to specialized cardiovascular services developed by the Department adopted by the Health Strategies Council and approved by the Board of Community Health.

(n) "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization.

(o) "Planning area" means each of the planning areas designated in the official State Component Plan.

(p) "Therapeutic cardiac catheterization" means the performance of cardiac catheterization for the purpose of ameliorating certain conditions that have been determined to exist in the heart or great arteries or veins of the heart.

(3) **Standards.**

(a) The need for new or expanded adult cardiac catheterization services shall be determined through application of a numerical need method and an analysis of service demand based on an assessment of the aggregate utilization rate of existing services;

1. the numerical need for new or expanded adult cardiac catheterization services shall be determined by a population-based formula which includes current usage patterns and projected population as follows:

(i) calculate the current state adult cardiac catheterization rate for the most recent year of reported survey or hospital and outpatient discharge data by dividing the total number of adult cardiac catheterizations performed on Georgia residents by the total state adult Resident population;

(ii) determine the projected adult cardiac catheterization procedures for the horizon year by multiplying the state rate by the adult Resident population for the planning area for the horizon year;

(iii) adjust the projected adult cardiac catheterization procedures for the planning area by adding the out-of-state hospital-based catheterizations for the most recent year based on the percentage of total procedures performed on out-of-state patients by hospitals in each planning area;

(iv) convert projected adult cardiac catheterization procedures to procedure equivalents by multiplying the projected procedures by the statewide rate of equivalents per catheterization; and

(v) determine the projected net surplus or deficit for adult cardiac catheterization capacity, expressed in terms of rooms/laboratories, in the planning area by subtracting the rooms/laboratories needed for the total projected procedure equivalents calculated in steps (i) through (iv) from the total capacity (1300 procedure equivalents per room/laboratory) based on the official inventory.

2. before a new or expanded adult cardiac catheterization service will be approved in any planning area, the aggregate utilization rate of all adult cardiac catheterization services in that planning area shall be 85 percent or more during the most recent year;

(b) 1. The Department may allow an exception to 111-2-2-.21(3)(a) in the following circumstances:

(i) actual utilization in the applicant's existing service has exceeded 90 percent of capacity over the past two years;

(ii) to remedy an atypical barrier to adult cardiac catheterization services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(I) An atypical barrier to services based on cost may include the failure of existing providers of adult cardiac catheterization services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state and/or planning area.

(II) An atypical barrier to services based on quality may include the failure of existing providers of adult cardiac catheterization services to provide services with outcomes generally in keeping with accepted clinical guidelines of the American College of Cardiology, peer review programs and comparable state rates for similar populations.

(III) An atypical barrier to services based on financial access may include the repeated failure, as exhibited by a documented pattern over two or more years prior to the submission of the application, of existing

providers of services within the community to provide services to indigent, charity and Medicaid patients.

(IV) An atypical barrier to services based on geographic accessibility may include a planning area which has an adult cardiac catheterization rate significantly less than the state rate (two or more standard deviations from the mean), a cardiovascular disease rate as projected through death and hospital discharge data which is significantly higher than the state rate (two or more standard deviations from the mean), and other demographic risk factors which can be documented through research and clinical studies.

(V) An applicant seeking approval for a new or expanded adult cardiac catheterization service solely for the purpose of providing cardiac electrophysiological studies may apply for consideration under the terms of an atypical barrier; provided, however, that any such applicant if approved shall be restricted to the provision of electrophysiological studies.

2. The Department may allow an exception to 111-2-2-.21(3)(a) and (3)(c) for any cardiac catheterization service seeking an expansion, other than the addition of another laboratory or room; provided the applicant complies with the general considerations and policies of 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with 111-2-2-.21(3)(d), (e), (f), (g), (h), (j), (k) and (l).

(c) An applicant for a new or expanded adult cardiac catheterization service shall document that authorized cardiac catheterization services which could be adversely impacted by the establishment of the new or expanded service are not predicted to perform less than 80 percent of capacity as a result of the establishment of the new or expanded service. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application.

(d) An applicant for a new or expanded adult catheterization service shall demonstrate a plan whereby the service and its medical staff agree to provide a full array of cardiovascular services to the community, including, but not limited to, education and outreach, prevention and screening, diagnosis and treatment, and rehabilitation.

(e) An applicant for a new or expanded adult cardiac catheterization services shall:

1. demonstrate the ability to meet the optimal clinical and physical environment standards established in the most recent American College of Cardiology/American Heart Association's Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories. These standards include, but are not limited to, physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with supporting emergency services;

2. document the availability of, or shall present a plan for recruiting, at least two board-certified cardiologists with training and qualification in cardiac

catheterization, and, if applicable with training and qualification in coronary intervention, who will reside within a one hour drive of the service site; and

3. document a plan for obtaining a sufficient number of clinical, professional and technical staff to safely and effectively operate the service.

(f) An authorized adult cardiac catheterization service shall not perform catheterization procedures requiring open heart surgery backup as part of its service unless the acute care hospital where the service is located:

1. operates an existing adult open heart surgery service; or

2. has a Department approved written agreement for open heart surgery backup with an adjacent acute care hospital as defined by these Rules.

3. has been accepted as a participant in a randomized medical research trial comparing patient outcomes after non-primary Percutaneous Coronary Intervention (PCI) in hospitals with and without cardiac surgery on-site, which also requires the performance of Primary PCI and has a parallel Primary PCI Registry, and which is coordinated by the Atlantic Cardiovascular-Patient Outcomes Research Team (Atlantic C-PORT). The authorized adult cardiac catheterization service must receive such Atlantic C-PORT acceptance and also must obtain written approval from the Department to perform such procedures, except that the Department may approve no more than ten (10) existing and authorized hospital services for participation, regardless of the number of such services that are accepted by Atlantic C-PORT.

(i) Any request for such Departmental approval must be submitted to the Department no later than June 30, 2005 in writing on a form developed by the Department for such purposes. Prior to final approval to participate by the Department, the requesting authorized service must provide written proof it has been accepted by Atlantic C-PORT as a participant in said trial under all applicable protocols;

(ii) In reviewing and approving such requests, the Department shall take into consideration such factors including, but not limited to, rural, suburban or urban location of the service, mix of patients to be treated, whether the service has the capability of performing a minimum of 100 PCIs (elective and primary combined) during the first year of such approval, 200 PCIs (elective and primary combined) during the second year of such approval unless a lower number, but not below 150 PCIs, is approved for specific reasons by both the Department and the trial chairperson, and 200 PCIs (elective and primary combined) during the third year of such approval, and whether the service has on its staff physicians and support staff with training and experience in both therapeutic and diagnostic cardiac catheterizations;

(iii) The selection of an authorized service for participation pursuant to this rule will be made at the sole discretion of the Department; however, the Department shall consult with medical experts in the fields of cardiology and percutaneous coronary intervention when making the decision to approve or not approve a particular service for participation in such trial;

(iv) Any approval obtained from the Department in this regard shall only be valid for as long as the health care facility receiving such approval is an active participant in the trial; however, in no case shall such approval continue to be valid upon Atlantic C-PORT declaring the trial concluded, or under no circumstance for a period in excess of three years from the time the authorized service's first procedure is conducted under the authority of the Department's approval and Atlantic C-PORT's acceptance to begin active participation in the trial; whichever event occurs first; and

(v) As any such Departmental approval is conditioned on being an active participant in the trial, should an authorized service which has received approval under the provisions of this rule be expelled or otherwise lose the approval of Atlantic C-PORT to continue participation, the Department's approval will be simultaneously withdrawn without said service's or facility's right to an appeal of the Department's withdrawal of its approval to participate in such trial.

(g) Catheterization procedures requiring open heart surgery backup include coronary angioplasty and the following:

1. catheter atherectomy;

2. catheter endomyocardial biopsy;

3. left ventricular puncture;

4. percutaneous transluminal coronary angioplasty;

5. percutaneous catheter balloon valvuloplasty; and

6. transeptal catheterization.

(h) An applicant for a new or expanded adult cardiac catheterization service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac catheterization services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area; and

2. propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) A clinical intervention program for all catheterization patients that shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives; and

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.

(ii) The program, if not operated by a facility with an existing Open Heart Surgical Service, shall submit a written affiliation agreement with at least one Open Heart Surgical Service that provides, at a minimum, for:

(I) a plan to transport and handle acute cardiac emergencies;

(II) a plan to facilitate referral of patients for whom surgery or angioplasty may be indicated without unnecessarily repeating diagnostic studies; and

(III) a plan for ongoing communications between representatives of the Open Heart Surgical Service and the proposed applicant, to allow for review of pre-operative and post-operative processes and specific cases.

(iii) The program shall provide for annual support and participation in at least three professional education programs targeted to community based health professionals, related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.

(iv) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors.

3. propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(i) An applicant for a new or expanded adult cardiac catheterization service must project and, if approved, shall document that the proposed service will be performing a minimum of 1040 adult cardiac catheterization procedure equivalents within three years of initiation of the service and annually thereafter within the authorized guidelines for such services. Such projections, at a minimum, shall include consideration of patient origin data for catheterization services, the use rate of existing services, referral data and market patterns for existing hospital and DTRC services in the community, and cardiovascular disease incidence rates and related health indicators. An applicant seeking approval solely for the purpose of providing electrophysiological (EP) studies shall not be required to document a projected performance minimum but shall be required to document compliance with guidelines for EP studies issued by the American College of Cardiology

(j) An applicant for a new or expanded adult cardiac catheterization service shall provide documentation that the service is fully accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) or, in the case of an applicant proposing a new facility location, shall provide a written commitment to secure full accreditation by JCAHO within eighteen (18) months of initiating operation.

(k) An applicant for a new or expanded adult cardiac catheterization service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant to include disease prevention and intervention services outlined in 111-2-2-.21(3)((h), that such services shall be provided regardless of race, age, sex, creed, religion, disability or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy; and

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent of annual, adjusted gross revenues for the adult cardiac catheterization service, or the applicant may request that the Department consider allowing the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid, Peach Care and Medicare programs and to accept any Medicaid-, Peach Care- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The

applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(l) An applicant for a new or expanded adult cardiac catheterization service must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs;

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital or DTRC as well as a national, state or multi-program system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital or DTRC;

3. development of procedures to ensure that cardiologists and any other physicians providing care in the cardiac catheterization service or related services shall be required to accept Medicaid, Peach Care and Medicare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(m) The department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

#19
Charles Beaman, Jr. – Palmetto Health

PALMETTO HEALTH

Ms. Mary Fechtel
Office of Certificate of Need
& State Health Planning Committee
SC DHEC
2600 Bull Street
Columbia, SC 29201

RE: 2008 State Health Plan Comments

Dear Ms. Fechtel:

On behalf of Palmetto Health I would like to thank you for this opportunity to provide comments related to the new State Health Plan. We at Palmetto Health value the importance of having a well defined planning process for South Carolina and want to ensure the integrity is upheld. For that reason, I am submitting the following comments for the 2008 State Health Plan.

General Hospital Beds
Page II-7
Palmetto Health supports the new standards for calculating bed need for individual hospitals. Including an individual hospital's bed need irrespective of an overall county need provides the ability for regional referral centers to accommodate for their service area growth. Tertiary care hospitals serve a much larger area than the specific county in which they are located and consideration for increasing occupancy rates must be allowed. This change in methodology allows for this increased occupancy.

Additionally, a standard needs to be included that prevents non hospital entities from applying for excess beds that are shown as bed need for an individual hospital. Capital plans may prevent a facility from applying for the hospital's excess beds in the current year, but not subsequent years. An outside entity should not be allowed to obtain a Certificate of Need for a specific hospital's beds without the approval of the specific hospital.

Criteria for a New Hospital

Palmetto Health recommends that any new hospital must meet the minimum service criteria as outlined in the Plan. We would also support a requirement that all new hospitals accept Medicare and Medicaid and have an indigent care policy that is consistent with the community.

Long Term Acute Care Hospital
Pages II 21-23

The Draft State Health Plan does not provide a methodology for determining bed need for Long Term Acute Care Hospitals and has eliminated the need for bed conversion from acute care hospitals. While Standard Four (4) does requires a Certificate of Need to convert LTAH to acute care beds, Palmetto Health is recommending the language be strengthened to ensure that a bed need must exist in the service area for such a conversion to take place.

Neonatal Services
Page 11-31

Palmetto Health acknowledges the role of DHEC in the establishment of a highly specialized neonatal regionalization program. The State Health Plan confirms the limited need for these services requiring that they be planned for on a regionalized basis, fostering the location of the specialized units in medical centers, which have the necessary staff, equipment and consultative services and facilities. Referral networks should be established to facilitate the transfer of infants requiring this level of services from other facilities.

The organization of the DHEC regionalization program has worked well for the state of South Carolina. Where a need exists in Level III bassinets, Palmetto Health recommends that preference be given to established programs in South Carolina. These hospitals are experienced in the provision of critical care for a highly specialized service. Duplication of such programs could adversely impact the physician and staff manpower that is needed for such a critical service.

Cardiac Catheterization
Page II 41-51

Palmetto Health supports use of clinical research to benefit the health of South Carolina citizens. However, it is our belief the use of the C-PORT study, as it is being proposed in South Carolina, is an attempt for hospitals that provide diagnostic catheterizations to develop interventional programs.

The American College of Cardiology does not endorse the performance of elective percutaneous coronary intervention in a setting without open heart surgery capability on site.[1] Thus, Palmetto Health does not support the CON approval for these studies in South Carolina and recommends deleting Section Nine (9) from the State Health Plan.

Open Heart Surgery
Page II 52-58

[1] http://www.acc.org/qualityandscience/clinical/guidelines/percutaneous_execsumm/perc_iv.htm

Open heart surgery services are available within sixty (60) minutes travel time for the majority of residents of South Carolina. Open heart procedure volumes have decreased statewide over the last three years. The benefits from improved access by initiating new programs would not outweigh the adverse impact on the existing programs. Palmetto Health continues to support the existing standards for open heart surgery in the Draft 2008 State Health Plan.

Standard (5) B.1. changes the standard for the number of required diagnostic catheterizations needed to generate the minimum volume of 200 open heart surgeries. This new standard, which is based on the last three years of data, is established as one (1) surgery for every seven (7) diagnostic cardiac catheterizations. This increases the minimum required diagnostic catheterization volume to 1400 procedures that a facility would need to perform to ensure that a minimum of 200 open heart procedures would be performed. This new standard needs to be stated in the State Health Plan.

Gamma Knife
Page II-64

While "GammaKnife" is the gold standard treatment for radiosurgery, radiosurgery can also be performed with (1) a dedicated linear accelerator equipped for such service; (2) a robotic device for the radiation emitter (as in cyberknife); or (3) a machine delivering gamma rays using a cobalt source (Elekta's GammaKnife or American Radiosurgery' s "Rotating Gamma System").

All of the above involve, by definition of radiosurgery, a surgical procedure directed by a neurosurgeon and a radiation oncologist. The entire procedure occurs in one day or more days, including immobilization, scanning, planning and the procedure itself. With radiosurgery, the radiation dose given in one session is usually less than the total dose that would be given with radiation therapy over several days. However, the tumor receives a very high one time dose of radiation with radiosurgery, versus smaller doses over time with radiotherapy.

The current State Health Plan confines the standards for radiosurgery equipment only to one source of radiosurgery, GammaKnife, and does not take into consideration the effect on need associated with either (2) a dedicated linear accelerator(s) equipped to do radiosurgery; or (2) robotic devices for the radiation emitter (cyberknife). As a consequence, the standards for radiosurgery need to be expanded and strengthened, since they are solely based on one method of delivery of radiosurgery.

Furthermore, the standards for GammaKnife, in our view, are not entirely representative of current technology. The threshold projection of 300 cases per service is based on very conservative estimates of capacity. The new state of the art GammaKnife reduces the "in-treatment-room time" considerably. This throughput will make it highly likely that 3 to 4 cases can be performed in a given day, with adequate provisions made for case preparation and recovery in the radiosurgery suite and not in the treatment room itself.

Therefore, we respectfully request that the capacity threshold should remain at 500 cases, instead of being reduced to 300 cases.

In summary, we propose to DHEC that:

1. the radiosurgery CON Standards be written for all modalities of radiosurgery delivery in one comprehensive section, particularly as it applies to common anatomical sites treated, such as the brain; and
2. the cobalt source - delivered radiosurgery (Gamma Knife) threshold standard remain at 500 cases to reflect the current capacity improvements afforded by state of the art equipment.

MRI
Pages II 59-68

The State Health Plan has removed MRI as regulated equipment. Palmetto Health realizes that non-facility providers have increased and data are not reported; however, Palmetto Health does not support the removal of MRI from the State Health Plan. The potential impact on hospitals' outpatient business could be significant, especially in small community hospitals. Palmetto Health is recommending any new provider of MRI service apply for CON and document community need and adverse impact on current providers.

PET/PETCT
Pages II 69-70

Palmetto Health recommends that an applicant address potential adverse impact on existing providers in the service area. Any new scanner should not result in a current provider's volume falling below the minimum threshold of 750 procedures per year. Additionally, the applicant should provide an indigent care policy that is comparable to other health care facilities in the area.

Ambulatory Surgery Facilities
Pages II 72-74

The Draft provides a new Standard Eleven (11) that requires an indigent care policy like that for other facilities. Palmetto Health supports the inclusion of this requirement.

In the absence of volume standards, Palmetto Health recommends that DHEC revise Standard Three (3) to add: *That documentation and projections of market shifts must be shared with existing providers of surgical services in the county, and applicant must provide documentation that has occurred.*

Additionally, Palmetto Health proposes that DHEC revise Standard Six (6) to add: *To validate the projected impact, DHEC will survey all existing hospitals and free standing*

ASFs in the county concerning existing capacity and need. The results of these surveys will be a factor in evaluating possible adverse effects of duplication of service.

Palmetto Health would also recommend that DHEC give preference to hospital owned or hospital – physician joint ventured facilities. Hospitals' charitable missions provide a higher probability of providing services to the poor and underserved.

Emergency Service
Pages II -81-83

The State Health Plan acknowledges that "All segments of the population should have basic emergency services available within 30 minutes one-way travel time." Palmetto Health supports removal of Standard Three (3),"The proposed freestanding emergency service must be locate no closer than 30 miles from an existing hospital emergency department or off-campus emergency services."

Any off-campus emergency service should require Certificate of Need. However, establishing a mile designation for a free standing emergency room could limit the access to certain segments in the state.

Additionally, Palmetto Health advocates that free standing emergency services be evaluated based on community need irrespective of county line divisions. There are several counties within the state where no hospital exists. Limiting the establishment of a free standing emergency service by an existing hospital within the same county would not meet the needs of the people in that county. However, Palmetto Health does recommend that any free standing emergency service be established by a hospital that is licensed and in good standing in the state of South Carolina. We would propose adding language that would give preference to a South Carolina licensed hospital over an independent provider.

Thank you again for allowing Palmetto Health to provide comments regarding the Draft 2008 State Health Plan. If you have questions concerning these comments, please do you hesitate to contact me at 296-5042.

Best regards,

Charles D. Beaman, Jr.
Chief Executive Officer
Palmetto Health

#20
Elizabeth Fletcher – Spartanburg Regional Healthcare System

SPARTANBURG
Regional Healthcare System

February 29, 2008

Gerald A. Wilson, M.D., Chairman
S.C. State Health Planning Committee
S.C. Department of Health and Environmental Control
Division of Planning and Certification of Need
1777 St. Julian Place, Suite 201
Columbia, SC 29204

Dear Dr. Wilson:

Thank you for the opportunity to comment on the Draft 2008 – 2009 South Carolina Health Plan. I am writing to submit the comments of the Spartanburg Regional Healthcare System regarding the Draft Plan. Our comments are as follows:

Chapter II

G(1). General Medical Facilities and Services

General Hospitals

In section 1. (A) (4) (d, e), Spartanburg Regional Healthcare System supports the reduction in the maximum beds which may be added for an economical unit from 50 beds to 30 beds.

Limited Service Hospitals

The 2007 Draft Plan included a requirement that any new hospital must be a general hospital with a Level III Emergency Room. However, this requirement is not included in the 2008 – 2009 Draft Plan. SRHS suggests the requirement be placed back into the 2008- 2009 Plan in order to ensure quality patient care. A recent report by the Department of Health and Human Services' OIG concluded that limited-service hospitals are not prepared to handle emergencies.

Long Term Care Hospitals

Under the current Plan, LTAC beds must be converted from existing general hospital beds. In the 2008-2009 Draft Plan, this requirement was removed due to revised CMS policies. For consistency purposes, SRHS suggests revising Standard 4 to include rehab beds and psych beds. "A Certificate of Need is required to covert LTACH beds to general acute care beds, rehab beds or psych beds."

101 East Wood Street • Spartanburg, South Carolina 29303 • 864-560-6000 Fax 864-560-6001

In addition, those hospitals which originally converted existing acute care beds to LTAC beds and who no longer wish to operate LTAC beds should have the opportunity to convert the LTAC beds back to acute care beds.

Furthermore, it should be noted that with the 2008 – 2009 Draft Plan, the potential exists for a provider to obtain LTAC beds and later convert the LTAC hospital into a limited-specialty hospital without CON review. Therefore, SRHS recommends a new standard which requires the new LTACH to become certified by CMS or the CON is void and the beds are de-licensed.

Cardiovascular Care

Cardiac Catheterization

Spartanburg Regional Healthcare System is concerned about the inclusion of standards for participation in the C-Port study of PCI without on-site cardiac surgery. SRHS supports the American College of Cardiology and the American Heart Association which state that performing elective PCI without immediately available on-site cardiac surgery is not recommended. Although access to cardiac care is not an issue in South Carolina, patient safety is of utmost importance.

Open Heart Surgery

In the 2004 – 2005 South Carolina Health Plan, the third paragraph of Criteria 5 on Page II-54 read, "Therefore, the Department staff is directed to evaluate low-volume open heart surgery programs to monitor their progress and recommend to the State Health Planning Committee any changes deemed necessary by staff." This paragraph was removed in the Draft Plan. However, the first sentence of Criteria 5 in both plans read, "Research has shown a positive relationship between the volume of open heart surgeries performed annually at a facility and patient outcomes.

It is important to note that of the 17 open heart surgery programs, only 35% of the programs are meeting the minimum volume standards of 200 open heart surgeries per operating room and only 7% performed 350 surgeries in 2006. SRHS recommends the paragraph be returned to the Draft Plan and the Department monitor program volumes as directed.

Spartanburg Regional Healthcare System supports using the ratio of 7 diagnostic caths generate the need for 1 open heart surgery.

In addition, please note that the initial data reported for the Spartanburg Regional Medical Center open heart surgery volume was incorrect. The correct number of open heart surgeries for 2006 was 401. SHRS apologizes for the error and appreciates DHEC updating the data.

Megavoltage Radiotherapy & Radiosurgery

Spartanburg Regional Healthcare System supports the differentiation between standard radiation therapy services and specialized radiation therapy services. However, SRHS suggests that the planning capacity of a CyberKnife be reduced from 4,000 treatments per year to 900 treatments per year. Information from industry experts identifies the following volumes requirements are appropriate for new CyberKnife services.

Year One: 250 treatments
Year Two: 500 treatments
Year Three: 750 treatments

By Year Three, the unit should be operating at 80% of capacity.

Furthermore, for both Radiotherapy and Radiosurgery Equipment, a Standard should be included requiring the applicant for a new service to document where the potential patients will come from and where they are currently being served. Physician letters of support should come from those physicians who typically refer patients to these services.

Diagnostic Imaging

Magnetic Resonance Imaging

Spartanburg Regional Healthcare System recommends placing standards for MRI services back in the Draft Plan. SRHS believes the MRI standards should remain in effect for another health plan based upon the following concerns over unregulated access to MRI:

- Capital costs are decreasing for high-field MRI units and the availability of median age units is increasing making financial access to units very affordable for Independent Diagnostic Testing Facilities (IDTF) and/or physician office based purchases. This may lead to significant dilution of market and negatively impact hospital based facilities in maintaining required ownership or lease of fixed or mobile MRI units.

- Increased potential for over utilization of MRI procedures by private and for-profit arenas due to self-referral process and reduced payments under for profit reimbursement scales may further encourage over utilization or improper ordering practices.

- DRA (Deficit Reduction Act) strategies are not fully implemented at this point in time and proposed or scheduled regulatory implementations may negatively impact physician owned units to a point of placing such units in a situation of determining how to overcome the expense of ownership and operations versus inability to pay for unit.

Outpatient Facilities

Ambulatory Surgical Facility

There is a new Standard 11 for ASFs on Page II-74 which reads, "The applicant for a new ambulatory surgery facility must provide a written commitment that the facility will accept Medicare and Medicaid patients, and that un-reimbursed services for indigent and charity patients will be provided at a percentage which is comparable to other healthcare facilities in the service area."

SRHS suggests that a distinction be made for those ASFs which are joint ventures with a Not for Profit Hospital as joint venture ASFs contribute to their hospital partner.

In addition, in the second paragraph under Ambulatory Surgical Facility, SRHS requests the sentence beginning with "However, hospitals have expressed concern" be amended to read as follows: "Hospitals have expressed concern that ASF's, **which are not Hospital Joint Ventures**, are impacting their ability to fund their services." SRHS successfully participates in two joint venture ASFs.

Emergency Services

SRHS supports the inclusion of Standard 1 clarifying the requirement that a CON is required to establish a free standing emergency service.

SRHS supports Standard 2, but recommends clarification that the hospital and proposed free standing emergency service must be located in the same county.

In addition, SRHS recommends placing Standard 3 from the 2004 Plan back into the 2008-2009 Draft Plan and revising it to reflect minutes rather than miles as a more accurate measure of distance. "The proposed freestanding emergency service must be located no closer than 30 minutes from an existing hospital emergency department or off-campus emergency service."

As part of the documentation of need for a new free standing service, SRHS supports a requirement that the applicant document not only where the potential patients are coming from, but also why their access to emergency services are not adequate.

Thank you for the opportunity to provide comments on the Draft 2008-2009 South Carolina Health Plan. If you have any questions or require additional information, please do not hesitate to contact me at (864) 560-6110.

Sincerely,

Elizabeth B. Fletcher

Elizabeth B. Fletcher
Director of Planning

#21
F. Del Murphy Jr. – Carolinas Healthcare System, Charlotte

Carolinas HealthCare System

James E.S. Hynes
Chairman

Michael C. Tarwater, FACHE
Chief Executive Officer

Joseph G. Piemont
President & COO

February 29, 2008

Mr. Les Shelton
Division of Planning and Certificate of Need
S.C Department of Health and Environmental Control
and the S.C. State Health Planning Committee
1777 St. Julian Place, Suite 201
Columbia, South Carolina 29204

Re: Comments on the Draft 2008-2009 South Carolina Health Plan

Dear Mr. Shelton and Committee Members:

I appreciate the opportunity to provide comments regarding the Draft 2008-2009 South Carolina Health Plan on behalf of Carolinas HealthCare System (CHS). CHS is based in Charlotte, but operates numerous health care facilities in the state of South Carolina. In addition we operate hospitals located along the South Carolina border. As such, we have a keen interest in the South Carolina Health Plan and CON process. We offer the following comments for your consideration.

General Hospital Beds
CHS supports the revised methodology for calculating general hospital bed need. We also support the addition of paragraph (e) on page II-7 that allows any entity to apply for additional hospital beds when beds are needed in a county. In the past the Health Planning Committee considered a requirement that a new hospital be a general hospital. CHS supports that concept and proposes a qualified applicant be defined in the standards similar to what is included in the current North Carolina State Medical Facilities Plan on page 39. These requirements include: a 24-hour emergency department, inpatient medical services to surgical and non-surgical patients and services on a daily basis within at least five of the Major Diagnostic Categories as recognized by the Centers for Medicare and Medicaid Services.

Megavoltage Radiotherapy and Radiosurgery
The standards for radiotherapy equipment include a new capacity figure of 4,000 treatments per year for Cyberknife equipment. There are two Cyberknifes currently in operation at CHS

facilities: one at Roper St. Francis Healthcare in Charleston and one at CMC-NorthEast in Concord, North Carolina. We believe a more reasonable annual treatment capacity for a Cyberknife should be approximately 900 treatments per year. Alternatively, the annual capacity could be based on the number of patients treated on a radiosurgery machine. Other states have established capacity targets based on the annual number of patients treated which range from 250 and 325 patients per year.

Thank you again for the opportunity to participate in your process and provide comments regarding the Draft 2008-2009 South Carolina Health Plan. Should you have any questions regarding these comments, please call me at 704-355-6060.

Sincerely,

F. Del Murphy, Jr.
Vice President-Planning

#22
Sam Tolbert – Strategic Directions

STRATEGICDIRECTIONS
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115 Parkwood Road
Greenwood, SC 29646
Phone: 864.992.0084
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Email: STolbert@StrategicDirectionsInc.com

February 29, 2008

Les Shelton, Senior Planner
Bureau of Health Facilities and Service Development
SC Department of Health & Environmental Control
2600 Bull Street
Columbia, S.C. 29201

Subject: Comments on *Draft 2008-2009 South Carolina Health Plan*

Dear Mr. Shelton:

Please accept theses recommendations regarding the *Draft 2008-2009 South Carolina Health Plan.*

The following standards relating to ambulatory surgery facilities on pages II-73 -74 in the Draft Plan should be deleted:

(9) Before an application for a new Ambulatory Surgery Facility can be accepted for filing, all existing ASF's in the county where the proposed facility is to be located must have been licensed and operational for an entire year, and submitted data on the Department's annual questionnaire to allow for a determination of their utilization. The data will not be prorated or projected into the future but based on actual utilization. For purposes of this standard, endoscopy suites are considered separately from other operating rooms. Endoscopy-only ASF's do not impact other ASF's. Before additional licensed endoscopy suites can be added in a county, all ASF's with licensed endoscopy suites must have had these suites licensed and operational for one year to allow for a determination of the utilization of the endoscopy providers.

(10) In no case can more than one new ASF in a county be approved at a single time. The approval of a new ASF in a county does not preclude an existing facility from applying to expand its number of operating rooms and/or endoscopy suites.

These standards unduly restrict DHEC from approving additional ASF's to meet public need. Between 1999 and 2005, outpatient surgery procedures increased in SC by an average of 7% per year. In metropolitan areas with 15-20 existing outpatient surgery OR's, this growth creates the need to add 1-2 new OR's each year. When a new ASF is approved, the construction, licensing, subsequent one year of operation, and submission of utilization data to DHEC will typically take 3 years. If a CON approval is appealed, the time lapse can easily increase 1-2 more years.

During these years, demand is growing but no other new ASF's can be approved. When this occurs, the residents of South Carolina are greatly disserved by the CON process. I believe a better approach is to delete these two standards, require each applicant for a new ASF to

demonstrate its need, and give DHEC the latitude to approve new ASF's if the need is clearly proven.

In addition, Joe Mills, Director of Corporate Accounts for Accuray, Inc. has requested that I submitted the attached comments. He was unsuccessful in attempting to email them to you, so I am providing them with my support.

Respectfully submitted,

Sam Tolbert

Sam Tolbert

#23
Judith Cullison – Presbyterian Healthcare, Charlotte

Presbyterian HEALTHCARE

Remarkable People. Remarkable Medicine.

February 29, 2008

Gerald A. Wilson, M.D.
Chairman
South Carolina State Health Planning Committee
Division of Planning and Certificate of Need
S.C. Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Dear Dr. Wilson:

Thank you for the opportunity to comment on the Draft 2008-2009 South Carolina Health Plan.

Presbyterian Healthcare is a platinum sponsor of the South Carolina Hospital Association and is a healthcare system which consists of five hospitals in the Charlotte, NC area: Presbyterian Hospital our flagship tertiary care facility, Presbyterian Hospital Matthews, our 102 bed community hospital in South Charlotte in Matthews, NC, Presbyterian Hospital Huntersville, our community hospital just North of Charlotte, Presbyterian Orthopaedic Hospital, our orthopaedic specialty hospital across the street from Presbyterian Hospital in uptown Charlotte and Rowan Regional Medical Center in Salisbury, NC. All of these facilities are JCAHO accredited and many have received awards/recognition for the quality and compassion with which they deliver care such as the Ernest Codman award from JCAHO and the Professional Research Corporation's patient and employee satisfaction awards.

Presbyterian Healthcare also has filed an application for a Certificate of Need to build and operate a 64 bed hospital in York County. While our CON application was initially denied, we have an appeal pending before the Administrative Law Court and are committed to providing quality health care services in South Carolina through our South Carolina subsidiary, Presbyterian Hospital-York, LLC.

Therefore, Presbyterian Healthcare offers the following comments on the Plan:

Chapter I:

Introduction:

D. Relationship With Other Agencies, page I-2:

Presbyterian Healthcare recommends that the following paragraph from the 2004-2005 South Carolina Health Plan which has been deleted is added back into the proposed 2008-2009 Plan:

200 Hawthorne Lane, Post Office Box 33549, Charlotte, North Carolina 28233-3549 | 704.384.4000 | www.presbyterian.org
affiliated with Novant Health®

"The Department is conscious that the ultimate responsibility for administering this program cannot be shared with any individual or organization; however, it does recognize the valuable contributions that can be made by other interested organizations and individuals. For that reason it will be the policy to actively seek cooperation and guidance from anyone who wishes to comment on this plan."

This paragraph supports and reinforces the Department's request for comments from anyone on the Plan and the requirement for public hearing and comment contained in § 44-7-180(C) of the State Certificate of Need and Health Facility Licensure Act ("CON Act").

H. Relative Importance of Project Review Criteria, page I-3:

The phrase in the first sentence "In accordance with the latest revisions to the Certificate of Need and Health Facility Licensure Act," from the 2004-2005 Plan was deleted. Presbyterian Healthcare recommends that the Committee add this phrase back into the Plan. It is recommended that the Plan must be and remain consistent with the latest revisions to the Certificate of Need and Health Facility and Licensure Act.

Chapter II: Planning Regions and Facility Categories:

G.1.(a)(4) Narrative: General Hospital Beds, page II-7:

Presbyterian Healthcare supports the changes to the general hospital bed need methodology as drafted, except recommends the following change.

(4)(e) page II-7 the second sentence should read "*If the number of beds needed is less than **50** than up to a total of **50** beds could be approved for any entity at any location within the county.*" While 30 beds can be considered an economical unit it is Presbyterian Healthcare's position that to allow for staffing efficiencies, more flexibility and financial feasibility this number should be 50. Presbyterian Healthcare currently owns and operates Presbyterian Hospital Huntersville a 50 bed community hospital in Huntersville, NC. This facility is considered an excellent model of an efficient and effective hospital and has been designed with technological advances and quality initiatives to optimize patient access, satisfaction, quality and safety.

In addition, as written paragraph (4)(d) and (4)(e) on page II-7 of the proposed 2007 Plan are mutually exclusive. In order to clarify the Plan, Presbyterian Healthcare recommends the following language:

(4)(e) page II-7 "*If there is a need for additional hospital beds in the county, then any entity may appy to add these beds within the county **and any entity may be awarded the Certificate of Need for these beds.***"

(D)(1) Obstetrical Services, page II-26:

On page 11-30 the Committee deleted the statement "Facilities providing obstetrical services must meet licensing requirement and either the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or certification standards." Presbyterian Healthcare recommends that this statement is added back into the proposed Plan. This statement stresses the importance of meeting quality and safety

standards and is necessary to establish basic thresholds for obstetrical quality of care. As noted above, provision of quality health care is one of the four purposes of the CON Act.

(D)(2) Neonatal Services, page II-31:

The Committee deleted the statement from the 2004-2005 Plan on page II-34 "The existing bassinets in the preceding table and the table below are based on the number stated on the hospital license or approved under the Certificate of Need program." Presbyterian Healthcare recommends that this sentence is added back into the Plan as it clarifies the data in the tables.

(G) Megavoltage Radiotherapy & Radiosurgery, page II-59:

The standards for Radiosurgery Equipment on page II-64 number (1) indicate the capacity of a Radiosurgery unit shall be 300 procedures annually. This number seems inflated if it does not include SRS and IMRT/IGRT procedures. Presbyterian Healthcare recommends clarification on the definition of procedures used to reach capacity. It is suggested that the word "dedicated" be added before the word Radiosurgery in the first sentence. If not it is not a dedicated unit then it is recommended that 150-170 procedures annually should be the target.

In addition, on page II-67 it states the Gamma Knife will be overseen by a board-certified neurosurgeon ***and*** a board-certified radiation oncologist. Presbyterian recommends clarification as to who needs to be on the radioactive license.

(H) Positron Emission Tomography (PET) and PET/CT page II-69:

The following comments are offered by Cynthia Gilbert, a member of the Board of Directors of the South Carolina Radiation Quality Standards Association:

It is recommended that the last sentence of the first paragraph on page II-69 be changed to "It is quantitative and very sensitive, so only **small** amounts of isotopes are needed." This change is recommended because the word "tracer" is another word for radiopharmaceutical.

In addition, it should be noted in the last sentence of paragraph two on page II-69 that Medicare also reimburses for lymphoma. It is recommended that this language is added.

Please note that the operator of a PET/CT must be a nuclear medicine technologist certified with PET and a CT certification or nuclear medicine technologist dually certified in radiography. Otherwise two technologists must operate the scanner; one in nuclear medicine/PET and a radiographer. There are pathways for radiographers to cross train and sit for the PET certification in South Carolina.

On behalf of Presbyterian Healthcare we appreciate the opportunity to submit the above comments. Please contact me at 704-384-5213 if you have any questions in this regard.

Sincerely,

Judith A. Cullison
Business Planning Analyst Senior

Cc: Les Shelton, DHEC

#24
Valinda Rutledge – Bon Secours St. Francis Health System

BON SECOURS
ST. FRANCIS HEALTH SYSTEM

February 28, 2008

Gerald A Wilson, M.D., Chairman
South Carolina State Health Planning Committee
South Carolina Department of Health & Environmental Control
1777 St. Julian's Place, Suite 201
Columbia, SC 29204

Re: Draft 2008-2009 State Health Plan

Dear Dr. Wilson:

I am writing on behalf of Bon Secours St. Francis Health System ("St. Francis") to raise three issues with the draft 2008-2009 State Health Plan that I feel warrant additional consideration by the DHEC planning committee.

Acute Care Bed Need
Under the current 2004-2005 State Health Plan, hospitals that show need for additional beds may be approved to increase the bed complement up to the greater of 50 beds or the actual projected number of additional beds that are demonstrated in the plan, provided the hospital can document and demonstrate the need for the requested beds. The rationale for allowing beds in excess of the calculated need was to provide cost-efficient construction projects and to allow facilities to meet future needs with a single project.

The most recent 2008-2009 Draft Health Plan has modified this standard. The maximum number of beds that a facility can apply for if need is determined in the Health Plan has been reduced to the actual projected need or up to 30 additional beds. While lowering the number from 50 to 30 is accurate for expansion of existing buildings, it is not economically efficient for new construction of satellite hospitals.

If a facility has a calculated need for more than 30 beds and is planning a satellite hospital, the facility should be allowed to not only meet the entire calculated need, but to also be able to add a minimum of 50 beds in order to ensure economic viability and to more efficiently meet future needs without additional construction or renovation.

Since there is a significant lag in the data used to calculate the bed need, hospitals that are experiencing an increasing utilization trend do not have sufficient ability to meet the continued

need for additional beds. The current draft 2008-2009 Plan relies on 2006 utilization data. 2007 data may show need for even more beds than demonstrated in the current plan. By allowing providers to add up to 50 beds, rather than 30, for construction of satellite facilities, the bed need that will be demonstrated in future plans can be addressed in a single project. This proactive planning results in economical development for hospitals. This was the intent of the 50-bed provision and we urge the planning committee to make the following revisions to the plan:

On page II-7 standard (d) and (e) should be revised to read:

(d) If a county indicates a surplus of beds, then no additional beds will be approved unless an individual hospital in the county indicates a need for additional beds. Should an individual hospital indicate a need for additional beds, then a maximum of the actual projected bed need or up to 50 additional beds may be approved for that hospital to allow for the construction of an economical satellite hospital at either the existing hospital site or another site, if the existing hospital is relocating or has relocated in whole or in part to that site. For expansion of current buildings where an individual hospital indicates a need for additional beds, then a maximum of the actual projected bed need or up to 30 additional beds may be approved for that hospital or any hospital within the same hospital system to allow for expansion construction of existing buildings at that existing hospital site or at any site within the same hospital system. In either case, the hospital requesting the addition must document the need for additional beds beyond those indicated as needed by the methodology stated above, based on historical and projected utilization, as well as projected population growth or other factors demonstrating the need for the proposed beds. Additional beds will only be approved for the specific hospital indicating a need.

(e) If there is a need for additional hospital beds in the county, then any entity may apply to add these beds within the county. If the number of beds needed is less than 50, then up to a total of 50 beds could be approved for any for a construction of a satellite hospital at any location within the county. If the number of beds needed is less than 30, then up to a total of 30 beds could be approved for the expansion of any existing hospital building within the county. An applicant requesting additional beds beyond those indicated as needed by the methodology stated above, must document the need for additional beds based on historical and projected utilization, floor plan layouts, projected population growth that has not been considered in this Plan or other factors demonstrating the need for the proposed beds. It is up to the applicant to document the need and the potential negative impact on the existing facilities.

Long-Term Care Hospitals

The draft 2008-2009 Health Plan provides detailed standards addressing Long-Term Care Hospitals (LTCH). While these standards address a number of relevant aspects, one area deserves further clarification. Hospitals that have previously or intend to convert general acute care beds to LTCH should be able to retain those beds, regardless of the need calculation, upon

termination of the LTCH service. The following standard should be added to the LTCH section of the Health Plan.

On page II-22 standard 2) should be modified as follows:

2) Although Long Term Hospital beds are not considered to be a separate category for licensing purposes, they will be inventoried separately from general acute care hospital beds for planning purposes. A hospital that has leased general beds to a Long Term Care Hospital shall be entitled to regain these beds once the lease is terminated according to the following procedure:

(a) the hospital shall seek a certificate of need to regain the beds;

(b) the hospital shall not be required to show a need for the beds under the bed need methodology set forth at pages II-6 through II-19;

(c) the certificate of need shall be granted upon a showing by the hospital that the lease has terminated and that the hospital has a use for the beds without regard to the bed need methodology set forth at pages II-6 through II-19;

(d) Upon receipt of the certificate of need, the beds shall be re-licensed to the hospital. No entity other than the hospital which initially leased the general acute beds (or its successor) to the Long Term Care Hospital shall be entitled to obtain the rights to the beds upon termination of the lease.

Freestanding Emergency Services.

The draft plan at pages II-81 and II-82 has appropriately deleted the provision of the current plan which prohibits locating a freestanding emergency service closer than 30 miles from an existing hospital emergency service. No rigid geographic limit should be imposed, whether by way of mileage, driving time, or county boundaries. Having emergency services conveniently located is a great benefit to the people of South Carolina. Location issues should be decided on a case by case basis not by any rigid geographic rule. These services should be permitted wherever an applicant can demonstrate a need for them in the proposed location.

- Requiring that these services be more than 30 miles or 30 minutes from existing services will cause problems. Because of traffic conditions in many parts of the state, more than 30 minutes may be needed to travel only a few miles during certain times of the day. Delaying emergency services by 30 minutes can be harmful to patients with many conditions. Application of a driving time standard will be difficult and potentially expensive.

- Limiting freestanding emergency services to a hospital's home county is also harmful to patients. Many, if not most, hospitals in our state regularly serve patients from beyond

their home county. Patients will benefit if hospitals are free to locate free standing emergency services wherever a need for those services exists. There is not logical justification for limiting these services to a particular county.

Thank you for your careful consideration of these comments. If you have any questions, or require any additional information, please feel free to contact me at 864-255-1121.

Sincerely,

Valinda Rutledge

Valinda Rutledge
Chief Executive Officer
Bon Secours St. Francis Health System, Inc.

#25
Jane Pressley and Jim Van Hecke – Upstate South Carolina Recovery Center

UPSTATE SOUTH CAROLINA RECOVERY CENTER

REQUEST FOR COMBINING PLANNING SERVICE AREAS TO ALLOW FOR A REGIONAL SUBSTANCE USE DISORDER TREATMENT FACILITY

Interested parties in the Upstate have come together to look at the possibility of creating a regional substance use disorder treatment facility, perhaps housed at the soon-to-be-vacant Allen Bennett Hospital in Greer, SC. We would respectfully request that some provision be made in the new State Health Plan, currently under review, for a combining of Planning Service Areas to allow for a partnership between counties in multiple Planning Service Areas.

Whereas we do not yet know how many inpatient beds verses residential beds we would need in this new facility, the prospect of a regional partnership involving multiple counties across several Planning Service Areas creates a unique opportunity. Creating a mechanism in the new State Health Plan for such a regional effort would allow for creative new approaches to pressing health needs such as we are proposing with our Upstate South Carolina Recovery Center.

Thank you for your consideration of this request.

Project Contact Information:

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Furman-Pressly Consulting, LLC
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janepressly@charter.net

Jim Van Hecke
President, Addiction Recovery Institute
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#26
J. Timothy Browne – Loris Healthcare System

Loris Healthcare System

Loris Healthcare System

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Box 690001
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Loris Community Hospital

3655 Mitchell Street
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843.716.7000

Seacoast Medical Center

4000 Highway 9 East
Little River, SC 29566
843.390.8100

Center for Health & Fitness

3207 Casey Street
Loris, SC 29569
843.716.7111

Extended Care Center

3620 Stevens Street
Loris, SC 29569
843.716.7106

Family Health Center - Loris

3204 Casey Street
Loris, SC 29569
843.756.9292

Family Health Center - Mt. Olive

5260 Highway 9
Green Sea, SC 29545
843.392.9222

February 28, 2008

Gerald A Wilson, M.D., Chairman
South Carolina State Health Planning Committee
South Carolina Department of Health & Environmental Control
1777 St. Julian Place, Suite 201
Columbia, SC 29204

Re: Draft 2008-2009 State Health Plan

Dear Dr. Wilson:

Loris Healthcare System ("Loris") would like to raise an issue regarding the draft 2008-2009 State Health Plan that we hope the State Health Planning Committee will consider.

Acute Care Bed Need – the 50 bed provision should not be reduced to 30.

The current 2004-2005 State Health Plan allows hospitals with a need for additional beds to seek up to the greater of 50 beds or the actual projected number of additional beds that are demonstrated in the Plan, provided the hospital can document and demonstrate the need for the requested beds. The rationale for allowing beds in excess of the calculated need was to provide cost-efficient construction projects and to allow facilities to meet future needs with a single project.

The most recent 2008-2009 Draft Health Plan has reduced the flexibility provided by this provision by reducing the 50 bed provision to only 30 beds. The maximum number of beds that a facility can apply for if need is determined in the Health Plan has been reduced to the actual projected need or up to **30** additional beds. By lowering the number from 50 to 30, the new standard limits hospitals' ability to develop a long-term, economically-efficient bed addition project. It may also cause problems for hospitals that have already made plans and, perhaps, even shelled in space in reliance on the 50 bed provision.

If a facility has a calculated need for more than 30 beds, developing a bed addition to meet that number will likely prove to be difficult. Rather than developing a single 20 to 25-bed unit and leaving the excess beds undeveloped, facilities should be allowed to develop two nursing units to not only meet the entire calculated need, but to also be able to meet future needs without additional construction or renovation.

Since there is a significant lag in the data used to calculate the bed need, hospitals that are experiencing an increasing utilization trend do not have sufficient ability to meet the continued need for additional beds. The current draft 2008-2009 Plan relies on 2006 utilization data. The 2007 data may show need for even more beds than demonstrated in the current Plan. By allowing providers to add up to 50 beds, rather than 30, the bed need that will be demonstrated in future Plans can be addressed in a single project. This proactive planning results in economical development for hospitals. This was the intent of the 50-bed provision and we urge the planning committee to make the following revisions to the Plan:

On page II-7, standards (d) and (e) should be revised to read [revisions in boldface]:

(d) If a county indicates a surplus of beds, then no additional beds will be approved unless an individual hospital in the county indicates a need for additional beds. Should an individual hospital indicate a need for additional beds, then a maximum of the actual projected bed need or up to **50** additional beds may be approved for that hospital to allow for the construction of an economical unit at either the existing hospital site or another site, if the existing hospital is relocating or has relocated in whole or in part to that site. The hospital requesting the addition must document the need for additional beds beyond those indicated as needed by the methodology stated above, based on historical and projected utilization, as well as projected population growth or other factors demonstrating the need for the proposed beds. Additional beds will only be approved for the specific hospital indicating a need.

(e) If there is a need for additional hospital beds in the county, then any entity may apply to add these beds within the county. If the number of beds needed is less than 50, then up to a total of **50** beds could be approved for any entity at any location within the county. An applicant requesting additional beds beyond those indicated as needed by the methodology stated above, must document the need for additional beds based on historical and projected utilization, floor plan layouts, projected population growth that has not been considered in this Plan or other factors demonstrating the need for the proposed beds. It is up to the applicant to document the need and the potential negative impact on the existing facilities.

Sincerely,

J. Timothy Browne

J. Timothy Browne
Chief Executive Officer

#27
Bruce Bailey – Georgetown Hospital System

GEORGETOWN
HOSPITAL SYSTEM

RECEIVED
FEB 29 2008

February 28, 2008

VIA HAND DELIVERY
Les Shelton
South Carolina Department of Health
and Environmental Control
1777 St. Julian Place, Suite 201
Columbia, SC 29204

RE: Draft 2008-09 State Health Plan

Dear Mr. Shelton:

I am writing on behalf of Georgetown Memorial Hospital ("GMH") concerning the draft 2008-09 South Carolina Health Plan. GMH has several recommendations concerning the draft Plan.

1. **Open Heart Surgery**

Proposed Standard 5(B)(1), on page II-53 of the draft Plan, requires a CON applicant for a new open heart surgery program to demonstrate a 7 x 1 ratio of diagnostic caths to projected open heart surgeries. GMH recommends that this proposed standard be deleted, for the following reasons:

a) While the apparent purpose of the ratio requirement is to ensure that a new program can perform 200 procedures within three years, more reliable ways exist to ensure sufficient volume. For example, a CON applicant may be able to document that each year many residents of its proposed service area undergo open heart surgery, and that its new program would capture at least 200 such patients within three years of initiation.

b) GMH is unaware of any other state that has a CON requirement based on demonstrating a ratio of diagnostic caths to open heart surgeries. GMH is unaware of any clinical studies suggesting that a 7 x 1 ratio reflects the appropriate balance between caths and open heart procedures.

c) Such a standard, based on the current statewide ratio, merely reflects (and perpetuates) the status quo. It is not a reliable indicator of need and would likely result in no new open heart programs being approved in South Carolina.

d) The proposed standard assumes that a diagnostic cath is a prerequisite for open heart surgery. This assumption is false, however, due in large part to the increased reliance on cardiac CTs.

e) The ratio of diagnostic caths to open heart surgeries is not only an unreliable indicator of need, it is highly susceptible to fluctuation.

For all these reasons, GMH recommends that proposed Standard 5(B)(1) be deleted.

2. C-PORT Study

Standard 9 of the cardiac cath standards in the draft Plan (p. II-45) allows for three hospitals statewide to be approved for a CON to provide PCIs without open heart surgery backup, for the purpose of participation in the C-PORT study. Standard 9(E) restricts the CON, however, to a maximum of three years "from the time the first procedure was preformed [sic]." GMH is concerned that, while the study is estimated to take three years, it could take longer. It would be detrimental to the study and the public if the participating hospitals were forced to drop out before the study's completion. For these reasons, GMH recommends that the first sentence of Standard 9(E) be revised to the following:

> The applicant, if approved, would be allowed to provide PCIs without open heart surgery back-up as part of the study until the study is completed.

3. Freestanding ERs

The draft Plan deletes the requirement that a freestanding emergency department cannot be located within 30 miles of an existing hospital. Because of the potentially significant adverse impact that a freestanding ER could have on an existing hospital, GMH recommends that the 30-mile requirement in the 2004-05 Plan be reinstated. In addition, GMH recommends that approval of a CON for a freestanding ER be contingent upon a demonstration of need and be limited to an extension of the emergency services of an existing hospital in the same county.

4. Radiation Therapy

The draft Plan, like the current Plan, imposes different standards on a "new radiotherapy service" and an "existing service." GMH recommends that the Plan clarify that an "existing service" may provide services at more than one location, by revising Standard 5 on page II-62 as follows:

> Expansion of an existing service, whether the expansion occurs at the existing site or at an alternate location in the service area, shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for the past two years and can project a

> minimum use rate of 50 percent of capacity per year on the additional equipment within three years of its implementation.

By its use of the verb "is providing", the second sentence of Standard 2 on page II-62 could be construed as applying only to providers already providing specialized radiotherapy services. GMH therefore recommends that the second sentence of Standard 2 be revised to read as follows:

> A facility must document that it is providing or will provide these specialized treatments in sufficient volume to justify why it should be held to this planning capacity.

To clarify the Department's position that all radiotherapy services in a given service area have the potential to affect one another, GMH recommends adding the following statement to the radiotherapy section on page II-60.

> Specialized radiotherapy techniques and modalities such as total body irradiation, IMRT, and Cyberknives may have an adverse impact on the utilization of existing standard linear accelerators.

We appreciate the Department's consideration of these recommendations. Please call me if you have any questions.

Very truly yours,

Bruce P. Bailey

BPB:nal

cc: Mary W. Fechtel
Beverly Patterson
Gayle L. Resetar
Rick Kaylor

#28
Stuart Smith – Medical University of South Carolina

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February 28, 2008

Mr. Les Shelton
Division of Planning and Certificate of Need
South Carolina Department of Health & Environmental Control
1777 St. Julian's Place, Suite 201
Columbia, SC 29204

Re: Draft 2008-2009 State Health Plan

Dear Les:

I am writing on behalf of the Medical University Hospital Authority (MUHA) of the Medical University of South Carolina to raise several issues that I feel warrant additional consideration by the DHEC planning committee.

Gamma Knife
The need in the 2008-2009 State Health Plan for Gamma Knife services is under a new heading titled "Radiosurgery" services. While the proposed plan provides detailed review standards for the development of Gamma Knife services, the proposed language fails to reflect the unmet need for additional resources. The historical utilization of the sole provider is not an accurate measure for current or future need throughout the state.

Service Area
By defining the service area for Gamma Knife services as the entire state, the proposed standards fail to assure geographic access for residents of South Carolina. This is the only service that has such a broad geographic service area. Other regional service standards (Open Heart Surgery and Perinatal) refer to a defined planning area (multiple counties) or travel times (60 and 90 minutes respectively) when determining availability and access to services. A less broad service area definition should be developed for Gamma Knife services. Any of the other defined service areas in the health plan could be the appropriate service area (5 regional areas used for Perinatal services or a defined 90 minutes travel time). MUHA requests that the language below be inserted as new Standard 2 and the remaining standards be renumbered:

(2) *Gamma Knife services should be available within 90 minutes for the defined service area population.*

Historical Utilization
The historical utilization of a sole provider of Gamma Knife services is not an accurate measure for projecting future utilization of an additional provider. While Gamma Knife technology has been available for a number of years, the acceptance and adoption of the services has been slow. The number of individuals that could benefit from Gamma Knife surgery far exceeds the actual utilization. By looking only at the volumes and use rate for the sole existing provider, the true potential patient population is understated. MUHA requests that the language in Standard 2 (page II-64) of the Draft State Health Plan be amended to include the following:

A. *All existing units have performed at a combined use rate of 70 percent of capacity for the most recent year; and*

B. *An applicant must project that the proposed service will perform a minimum of 200 procedures annually within three years of initiation of services, without reducing the utilization of existing units below the 70 percent threshold. In cases where existing providers are performing below 70 percent of optimal utilization for the most recent two years, the applicant must document that it will not cause the existing service to fall more than 10 percent below its most recent utilization levels;*

Needs of Academic Medical Centers or Medical Residency Training Sites

MUHA serves as an academic training facility for numerous medical residency programs. With 49 different medical specialty residency training programs, the hospital serves as a valuable resource for educating and preparing future physicians. Specifically, Neurosurgical residents, Otolaryngology residents, and Radiation Oncology residents all benefits from on-site access to stereotactic training. MUHA is also initiating a Radiation Physics residency training program. Access to state-of-the-art technology and equipment is essential for such facilities. Therefore, MUHA requests that an additional Standard be added to include the following:

(8). *Because of the unique nature and limited need for the equipment, it is preferable that Gamma Knife services be located in or operated in conjunction with teaching hospitals that offer a complete range of oncology and neurosurgery services. A "teaching hospital" means a hospital which operates multiple (more than one) medical residency training programs for programs of graduate medical education accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) and maintains a written affiliation agreement with an accredited medical school located in South Carolina, or is owned and operated by an accredited medical school in South Carolina.*

Due to the fact that the adoption and utilization of Gamma Knife services are developing, it is important that an academic medical center or hospital affiliated with a medical school has the ability to provide Gamma Knife services. In addition, the ACGME and other accreditation bodies are requiring residency training sites to include stereotactic surgery experience to resident. These types of institutions have very high standards for offering the latest technology, not only to provide the best quality care to their patients but also to provide the highest quality training for their healthcare professionals.

Pediatric Cardiac Catheterization

The current planning capacity and utilization measures for pediatric cardiac catheterization services do not adequately capture the true utilization at MUHA. Pediatric cardiac catheterization procedures are inherently more complex and take longer to perform per case than adult procedures due to a variety of issues, including:

1) Small patient size, leading to longer time to achieve access.

2) Lack of cooperation and comfort issues has lead to the use of anesthesia in the vast majority of pediatric catheterizations, including electrophysiology studies, increasing procedure time.

3) Complex abnormal anatomy and hemodynamics, leading to the need for more catheters, combined left and right heart procedures, a long diagnostic study, and the ubiquitous use of biplane cine-angiography.

4) A high proportion of complex interventions, including balloon dilations of valves and vessels, stenting, and device defect closures.

5) Electrophysiology cases often include the need for a hemodynamic catheterization, and sometimes and non-EP intervention, particularly in patients with congenital heart disease.

6) Biopsies after pediatric heart transplant often involve hemodynamic measurements, the use of anesthesia and are always performed in a fully equipped biplane pediatric catheterization laboratory, rather than a "procedure room".

Additionally, half of the individuals in the Unites States with congenital heart disease (CHD) are adults. Although many of these patients have minimal residual defects and lead normal lives, many also have ongoing complex problems that require the expertise of a cardiologist who specializes in congenital heart disease. A few adult cardiologists have trained in this specialty, but the vast majority of the care is still delivered by Pediatric Cardiologists.

In 2000, a joint American College of Cardiology (ACC) and American Heart Association (AHA) conference, known as the "32nd Bethesda Conference" was held to address "Care of the Adult with Congenital Heart Disease" (ACHD). The following paragraph is excerpted from Page 1190 of that report which is attached to this document.

> *Catheterization laboratory—The provision of expert diagnostic and therapeutic cardiac catheterization skills for ACHD requires personnel specifically trained in ACHD and needed therapies as well as all aspects of adult acquired medical disease. Table 2 describes the types of patients who should have cardiac catheterizations performed in regional ACHD centers. The catheterization laboratory and its equipment, as well as the recovery and post-catheterization ward facilities, must be provided. Finally, to maintain excellence, the laboratories and personnel at regional ACHD centers should have continuous experience at sufficient levels of adult or pediatric CHD complexity and volume.*

In general, the only catheterization laboratories that meet all of these guidelines are pediatric and in Children's Hospitals. At MUSC, these adult procedures are performed in the pediatric catheterization lab. Since these ACHD cases are treated in the pediatric laboratories, they should be counted towards the pediatric case numbers. In addition, these ACHD cases are often very time consuming due to the anatomic complexity and frequent need for interventions.

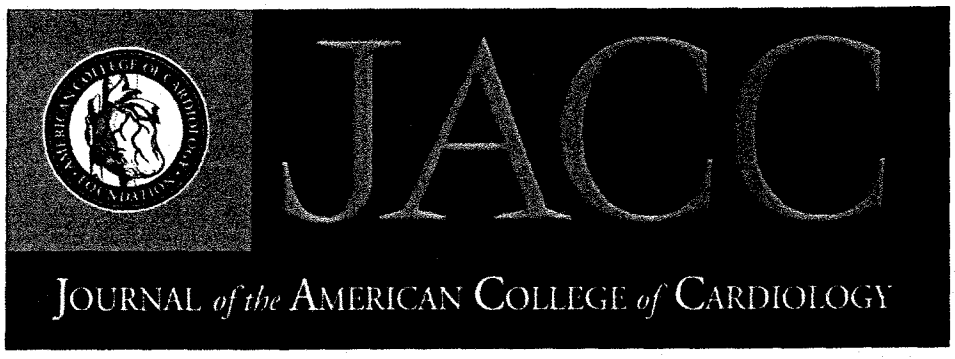
Given the above issues, we would recommend the following units for pediatric catheterizations, compared to the 1 unit per case count in adults:

Hemodynamics only - 2.0
Hemodynamics with intervention - 3.0
Electrophysiology - 3.0 (and should be counted as a cath procedure)
Biopsies - 1.0

Thank you for your careful consideration of these comments. If you have any questions, or require any additional information, please feel free to contact me at 843-792-4000.

Sincerely,

W. Stuart Smith
Vice President of Operations and
Executive Director of MUSC Medical Center



Task Force 4: organization of delivery systems for adults with congenital heart disease

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CONCLUSIONS

At present, the physician workforce caring for ACHD patients in the U.S. consists of a few (<20) adult cardiologists with advanced training, as described, and an ongoing career focus in ACHD, as well as a much larger number of adult and pediatric cardiologists with little or no specific training in the care of ACHD patients, but with on-the-job experience. Development of a small but highly trained cohort of ACHD specialists who could lead an integrated network of specialized centers would improve clinical care, advance knowledge, and help provide ongoing professional education for the larger population of adult and pediatric cardiologists who care for the majority of these patients.

Creating this population of ACHD specialists requires the clear articulation of training pathways and certification. Because of the long time required for training in CHD and adult diseases and research, some consolidation of training will be needed, in addition to the development of specific training funds and the establishment of debt relief to attract and maintain an adequate workforce.

RECOMMENDATIONS

- A joint task force of the ABIM and ABP, facilitated by the ACC, should be formed to determine the specific pathways and years of training required for Level 2 and 3 ACHD subspecialist cardiologists.
- Level 2 and 3 training programs should be coordinated to ensure the greatest learning opportunities for the ACHD cardiologists-in-training and to provide continuing education for trainees, graduates, and ACHD practitioners.
- ACHD research fellowships should be created so that individuals can spend 75% to 100% of their time in protected research over a two- to three-year period.
- Training programs for other key staff (e.g., nurses, physician assistants, psychologists, social workers, other nonphysician personnel) on ACHD teams should be established.

TASK FORCE 3 REFERENCE LIST

1. Congenital heart disease after childhood: an expanding patient population. Presented at the 22nd Bethesda Conference, Bethesda, Maryland, October 18–19, 1990. J Am Coll Cardiol 1991;18:311–42.
2. Perloff JK. Congenital heart disease in adults: a new cardiovascular subspecialty. Circulation 1991;84:1881–90.
3. Perloff JK, Miner PD. Specialized facilities for the comprehensive care of adults with congenital heart disease. In: Perloff JK, Child JS, editors. Congenital Heart Disease in Adults. Philadelphia: W. B. Saunders, 1998:9–12.
4. Beller GA, Bonow RO, Fuster V, et al. Guidelines for training in adult cardiovascular medicine: Core Cardiology Training Symposium (COCATS II). J Am Coll Cardiol. In press.

Task Force 4: Organization of Delivery Systems for Adults With Congenital Heart Disease

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ORGANIZATION OF DELIVERY SYSTEMS FOR ACHD

The delivery of appropriate care to adults with congenital heart disease (ACHD) is a largely unmet challenge in the U.S. and elsewhere. To meet this challenge, a structure and process for the organization and delivery of care is proposed. We will use the "severe heart failure care model" familiar to most cardiologists as an example of how the needs of ACHD patients can best be met. Similar to the challenge of the severe heart failure patients, ACHD patients have a low-to-moderate prevalence, need caregivers with both special knowledge of the conditions encompassed and the ability to provide tailored and out-of-the-ordinary treatments, and may require high-intensity medical care. By contrast to the heart failure population, ACHD patients reach age 18 at a rate of about 9,000 annually in the U.S. and may require much longer surveillance and care than most heart failure patients.

In this section we will: 1) describe the "severe heart failure model" that we propose should be emulated for ACHD patients, 2) describe the structure of such a program based on the concept of regional ACHD centers across the U.S., 3) outline the resources (services and personnel) required in such centers, 4) propose responsibilities for different types of physicians in the care of these patients, 5) describe the initial patient visit and its goals, 6) propose strategies for long-term follow-up, 7) and make some comments regarding hospitalization of these patients.

SEVERE HEART FAILURE AS A MODEL OF REGIONALIZATION AND CENTRALIZATION

The established "local caregiver or center supported by a regional specialized center" model for the organization and delivery of care for adult patients with severe heart failure serves as a paradigm for our proposal for a system of care for ACHD. When compared with the average cardiology patient, those with severe heart failure tend to carry high

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levels of medical complexity and incidence of recurrent illness, and they have less-optimal outcomes.

Given the supposition by internists and cardiologists that a great deal of heart failure management falls within their own expertise, patient care, including that for the most severely ill, previously tended to be spread throughout all levels of adult cardiovascular care. This model tended to limit the capacity to expand services, apply new knowledge, share experiences, and compare outcomes. The organization of best practice guidelines was difficult, and translation of such recommendations to everyday care was limited. Improvement in average care was gradual.

Because of a growing accountability to third-party payers and limited organ donor procurement, a new model for organizing and delivering care to the most severely ill arose, centered around a specialized regional program and working in conjunction with local providers of care. This system has evolved over a 20-year period, fulfilling most expectations for the provision of high-quality care. The severe heart failure model has allowed for: 1) improved teaching, collection, and dissemination of knowledge regarding heart failure and its ramifications; 2) new treatments, many of which could not be tested without sufficient numbers of patients and resources; 3) decreased outpatient visits, fewer hospitalizations, and improved patient quality of life; 4) improved medical and surgical outcomes; 5) containment of costs; 6) a more uniform pattern of medical care (allowing improved cooperation and cross-referral of patients and better definition of the appropriateness of medical and surgical care at a local, compared with a regional, center); and 7) a greater interaction between third-party payers, insurers, and medical caregivers.

This model has required the growth and development of both a national registry and regional databases to collect, organize, interpret, and distribute standardized and requested information and to review this in a timely fashion. Individual institutions maintain financial commitments to the maintenance of the databases and to the employment of medically savvy data collection and entry personnel. All institutions have access to their individual data and have the opportunity to initiate issue-driven research. Evidence-based recommendations can be generated with actual data and analysis requested by and determined in large part by the medical caregivers themselves.

The local and regional model of medical care functions well for this relatively small group of patients in need of expert and evidence-based care. A similar system will allow caregivers for ACHD to achieve the same rewards already obtained for adults with severe heart failure.

EVALUATION OF QUALITY

Health care quality has been classified into three components: structure (training and skills of personnel, adequacy of diagnostic and therapeutic equipment resources, and organizational systems that mobilize these resources most efficiently for optimal patient care), process (the use of appropriate diagnostic and therapeutic modalities for individual patients), and outcomes (the consequences of treatment).

PROPOSED STRUCTURE OF THE HEALTH CARE DELIVERY SYSTEM FOR ADULTS WITH CONGENITAL HEART DISEASE

An algorithm for the initial evaluation and ongoing care of ACHD is proposed. These recommendations include the subdivision and coordination of care of ACHD both locally and at regional ACHD centers. This model requires a system of data storage, rapid communication, critical self-analysis, establishment and implementation of practice guidelines, and insights to provide for the coordination of optimal current and future care of ACHD.

LOCAL (INDIVIDUAL PHYSICIAN AND CARDIOLOGIST)

Local medical resources for ACHD may be a family doctor, an internist, or a general cardiologist on the one hand, and an ACHD cardiologist with a commitment to, training in, and/or experience with the care of ACHD on the other. The first three groups of physicians will usually have a major or exclusive role in the types of patients listed in Table 6 of Task Force #1. These local clinicians might also participate in the care of adults with moderate and complex CHD (Tables 4 and 5 of Task Force #1) in collaboration with the staff of a regional ACHD center.

The ACHD cardiologists (who also practice as pediatric or adult medical cardiologists) can care for any ACHD patient. At present, the majority of ACHD cardiologists will have had informal training and on-the-job experience in the care of ACHD (see Task Force #3). More recently, a few training centers have produced ACHD cardiologists with comprehensive training and often a commitment to contribute academically to the ACHD discipline.

THE REGIONAL ACHD CENTER

A regional ACHD center is usually directed by an ACHD cardiologist who is supported by a collaborative, multidisciplinary team involving other cardiologists, mid-level practitioners, congenital heart surgeons, and others. The specific components of such a program are outlined in Table 1. Regional ACHD centers will frequently serve as the entry point for ACHD. They may receive patients from sources such as general pediatric and adult medical cardiologists, other specialists (e.g., obstetricians), primary care providers, patient self-referrals, and medical insurers. Every ACHD patient should be evaluated at least once by an ACHD cardiologist for the purpose of initial evaluation and recommendations for long-term care. Ideally, this applies even to the patients in Table 6 of Task Force #1, so-called simple CHD. This is particularly true for patients who have not been under the care of pediatric cardiologists. The goal of

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Table 1. Personnel and Services Recommended or Required for Regional ACHD Centers

Type of Service or Personnel	Local Care	Regional ACHD Center
Pediatric ACHD cardiologist	Optional	One or several 24/7*
Adult medical ACHD cardiologist	Optional	One or several 24/7*
Mid-level practitioner	Optional	Two/several
Congenital heart surgeon	No	Two/several 24/7*
Cardiac anesthesia	No	Several 24/7*
Echocardiography** Includes TEE, intraoperative TEE (required for surgery)	Refer to regional ACHD center	Two/several 24/7*
Diagnostic catheterization**	Refer to regional ACHD center	Yes 24/7*
Noncoronary interventional catheterization**	Refer to regional ACHD center	Yes 24/7*
Electrophysiology**	Consult regional ACHD center unless unrelated to CHD	Yes 24/7*
Exercise testing	Standard	Echo, radionuclide, cardiopulmonary, metabolic
Transplant	Optional	Heart, lung, heart-lung desirable
Cardiac imaging/radiology services	Optional	CT scan, cardiac MRI with fast-pulse sequencing*, nuclear medicine
Cardiac pathology	Optional	Yes
Information technology	Optional • Interface with regional ACHD center • Data collection • Participation in patient-care and best-practice guidelines review	• Data collection • Database support • Interface with local practitioners, including internet-based applications • Quality assessment review and protocols • Optional development of best practice guidelines
Other		• Adolescent transitional unit • High risk obstetrics • Genetics • Rehabilitation services • Social services • Vocational services • Financial counselors

* "24/7" denotes availability 24 hours/day, 7 days/week. **These modalities must be supervised/performed and interpreted by physicians with specific skills and knowledge in CHD, as outlined.

the visit is to ensure that other diagnoses or subtle but important findings have not been missed. Too often, patients with "simple" CHD are seen who have been misdiagnosed, mismanaged, or misinformed. Caregiver and insurance referral patterns will often require reconfiguration for referral to caregivers with specific expertise in ACHD care.

Regional ACHD centers may be established within an adult hospital, a children's hospital, a unit shared by both children and adult hospital facilities, or a freestanding unit. Such centers must afford prompt access for patients and referring physicians in order to provide:

Comprehensive diagnosis—All modes of cardiac diagnosis should be available. Each component of the diagnostic evaluation should be performed by individuals with appropriate training and experience in CHD.

Management planning—Best decisions have traditionally occurred within the venue of a case-management conference, at which personnel from cardiology, cardiac surgery, anesthesia, intensive care, and nursing review relevant data. Case-management conferences with discussion and consensus are very important in determining care strategy (including both the nature and timing of intervention) as well as educating and building the cohesion of team members.

Patient counseling—Within a regional ACHD center adults with CHD should participate in an informed discussion of their current medical/cardiac situation and their proposed management plan.

Specific personnel and services within regional ACHD centers are also necessary, including:

Cardiac anesthesia—The presence of a cardiac anesthesia team that offers consultative services, interacts with other members of the ACHD caregiving team, and anesthetizes patients with CHD is required.

Operating rooms—Operating facilities with prompt or immediate access to all perioperative (e.g., echocardiography, catheterization) and intraoperative (e.g., transesophageal echocardiography) diagnostic procedures are essential. Dedicated fully trained congenital cardiac perfusionists (with expertise in VAD and ECMO setup, delivery, and maintenance) are mandatory.

Cardiac surgery—In addition to adult cardiovascular surgeons, regional ACHD centers require the availability of full-time, expert congenital heart surgeons. At least two congenital heart surgeons (often based primarily at a children's hospital) are required to provide 24-h coverage for both the pediatric and adult facilities. Their surgical teams should be expected to maintain their expertise through performing a critical annual volume of pediatric and ACHD surgeries.

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Intensive Care—ICU staff trained and expert in provision of care to ACHD are required in regional ACHD centers. The ICU should be sited with rapid access to the ORs and be capable of performing open-chest resuscitation and of implementing and monitoring ECMO and VAD. The ICU staff and residents/fellows can be culled from medical cardiology, cardiac anesthesia, cardiac surgery, and critical care specialties, and they should be supported by fellowship programs. Expert medical and surgical care should be on-site 24 h/day, 7 days/week. The skill of the staff in diagnosing and managing acquired cardiovascular and other diseases is very important here as well as throughout all units and services caring for ACHD patients. Timely access to all diagnostic services and interventions should be available 24 h/day. The ICU nursing staff should have specific expertise in the care and management of ACHD.

In-patient service—ACHD patients require a hospital environment with specifically qualified nursing staff and support personnel. This may be provided within the context of other medical or cardiology unit or on a unit dedicated to ACHD patient care. The unit should contain a high-intensity central nursing area with hemodynamic/electrocardiographic telemetry monitoring. Expert medical and surgical physician care should be either on-site or available in a near-immediate fashion 24 h/day, 7 days/week. Optimally, the in-hospital beds, ICU, cath lab, and ORs should be geographically clustered, in close proximity to noninvasive laboratories, outpatient areas, and cardiology/cardiac surgery administrative services. The center should support social workers and financial counselors, and it should make appropriate use of chaplaincy support.

Transplantation—Regional ACHD centers should be affiliated with a transplant program.

Catheterization laboratory—The provision of expert diagnostic and therapeutic cardiac catheterization skills for ACHD requires personnel specifically trained in ACHD and needed therapies as well as all aspects of adult acquired medical disease. Table 2 describes the types of patients who should have cardiac catheterizations performed in regional ACHD centers. The catheterization laboratory and its equipment, as well as the recovery and post-catheterization ward facilities, must be provided. Finally, to maintain excellence, the laboratories and personnel at regional ACHD centers should have continuous experience at sufficient levels of adult or pediatric CHD complexity and volume.

Noninvasive imaging service—24 h/day, 7 day/week coverage is required, with volume and complexity sufficient to maintain excellence in obtaining and interpreting echocardiographic, computerized tomographic, and magnetic resonance images of ACHD patients.

Electrophysiology service—A fully equipped and properly staffed service with a full range of ablative and pacing therapies, in addition to the consultative and diagnostic services appropriate to the special needs of ACHD patients, must be available.

Table 2. Types of Patients Needing Cardiac Catheterization in Regional ACHD Centers

The following cardiac catheterization procedures on ACHD should be performed at a regional ACHD center and by staff with sufficient training, expertise and support services (including congenital heart surgical backup):
All diagnostic catheter procedures with the exception of coronary angiography
Aortic coarctation/RV outflow/peripheral pulmonary stenosis dilation &/or stent placement
Congenital valve dilation
PDA closure
Septal defect closure
Vasodilator or vascular shunt/access occlusion trials
Venous pathway dilation or stent placement

High-risk obstetrics—24 h/day, 7 day/week coverage by staff expert in the counsel and care of women with CHD is a special requirement.

Cardiac pathology—Expertise in congenital cardiac pathology and post-mortem examination must be available within the regional ACHD centers.

GEOGRAPHIC DISTRIBUTION OF REGIONAL ACHD CENTERS

The proposed regionalization described in this report should provide appropriate and continuous access, when needed, to all types of care for all ACHD in the U.S. Because geographic regions of the U.S. vary in population density and available medical resources, some flexibility in applying the principles of regionalization is appropriate. As a rule, there should be approximately one regional ACHD center per population of 5 to 10 million people and approximately 30 to 50 regional ACHD centers nationwide. In some areas of the country, regional ACHD centers may be farther apart and may have somewhat smaller ACHD populations. In the largest urban centers with several pediatric cardiology and congenital heart surgical programs there are likely to be two or more regional ACHD centers. In all regions, reciprocal communication between regional ACHD centers, local caregivers, and patients is required. In recognition of the fact that particular areas of expertise may not be equally present in each regional ACHD center, specific geographic referral patterns may overlap different regions.

PROPOSED PROCESS FOR DELIVERY OF HEALTH CARE TO ACHD PATIENTS

Newly arrived ACHD patients. As described in the report of Task Force #2, an orderly transition of care from the pediatric to the adult facility is most strongly recommended. One of the many reasons for this is to reduce the number of patients lost to follow-up during adolescence and young adult life. The pediatric cardiologist should provide a copy of all relevant clinical records, including operative reports, catheterization reports, and the like, to the patients and the regional ACHD centers at the time of transfer to ACHD care.

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The initial patient evaluation. Patients may first present for CHD care in their adult years because they have new symptoms, functional deterioration, or a growing sense of the need to resume regular care.

An ACHD specialist should evaluate all adults with moderate and complex CHD (Tables 4 and 5 of Task Force #1) at least once and should also evaluate most patients with simple CHD (Table 6 of Task Force #1). The evaluation should include a thorough history, a review of documents outlining specific diagnoses and details of treatments applied, and any other clinical problems. In addition, a tailored clinical and laboratory evaluation should be performed to assess current patient status. This initial ACHD evaluation should also involve an extensive component of patient education regarding both the nature of the congenital abnormality and the anticipated unrepaired or postoperative course, along with instructions on when and how to access care in the future, especially in urgent situations. This consultation should result in a report to patients and their primary care and supporting physicians. This report will document the baseline evaluation and provide a contact for questions and other issues that may arise in the future. The initial ACHD evaluation allows stratification of these patients according to risk and management difficulty.

An ACHD cardiologist will review the history regarding acquired cardiovascular and other medical conditions. This should be part of each work-up and will increase in importance as a patient ages. For example, the development of coronary artery disease or high blood pressure is important not only in itself but also in its potentially adverse effect on the course of CHD in adults.

Long-term follow-up. Most ACHD patients will require intermittent regular evaluations at a regional ACHD center. Such patients will benefit by maintaining contact with a primary care physician and, in some cases, a local adult medical cardiologist. All reports generated at regional ACHD centers should be transmitted to patients and their local physicians and should include specific goals and responsibilities for local as well as regional ACHD follow-up. In some cases, when a patient lives close to a regional ACHD center, the ACHD cardiologist can function as a primary cardiologist, leaving other health care to the primary care physician.

It is not implied here that the regional ACHD center take over the care of all ACHD patients. The role of the regional center should be to take an appropriate role in the management of each patient (ranging from no role, through joint care, to exclusive and close care). In addition, it should be used as a source of expert advice and information.

For simplicity, three groups of patients are described according to the following scheme:

Lesions that can usually be cared for in the Community (Table 6 of Task Force #1) after initial expert evaluation, usually in a regional ACHD center. These patients with simple CHD are felt to be at low risk for new clinical problems. This group includes some patients with minor congenital abnormalities who have not undergone surgical or other intervention (e.g., mild pulmonary valve stenosis, small isolated ventricular septal defect) and patients with simple congenital defects who have undergone successful repair (e.g., repaired ductus arteriosus, ventricular septal defect or secundum atrial septal defect with no residual shunt or other sequelae). Patients in this category will usually be followed by either a primary care physician or a community cardiologist. If necessary, a patient could be referred to a regional ACHD center.

Adults with CHD with residual hemodynamic or structural abnormalities who are clinically stable (Tables 4 and 5 of Task Force #1). Most adults with moderate and complex CHD fall into this category. Each specific defect or combination of defects carries its own list of potential complications. Such patients require ongoing surveillance to detect any changes in status and/or increased risk profile. In addition, as clinical practice and research advance, new principles of patient management will be applied by the ACHD cardiologist at the regional ACHD center. Such patients benefit, as well, from care given by a primary caregiver who provides local ongoing care and who communicates and cooperates with the ACHD cardiologist. For some patients, clinical evaluations may alternate between the local provider and the regional ACHD center.

Adults with CHD may develop active cardiovascular problems or become clinically unstable. These problems should be addressed, whenever possible, at a regional ACHD center. The ACHD cardiologist should maintain primary clinical responsibility for these patients until their clinical status stabilizes. Examples include significant arrhythmias, ventricular dysfunction, significant valve regurgitation, and infective endocarditis. Interventions in such patients generally should be performed at regional ACHD centers.

Any adult with CHD who develops a new clinical problem that might be related to a cardiovascular abnormality should be referred for re-evaluation to, or be under the care of, a regional ACHD center. In addition, if intervention is required, most patients should be evaluated at their regional ACHD center before intervention. When appropriate, some procedures can be performed locally (for example, noncardiac surgery in an asymptomatic low-risk adult with CHD). Such an evaluation might also lead to a recommendation that the intervention be performed at a regional facility integrated with the regional ACHD center.

FREQUENCY OF PATIENT FOLLOW-UP

For adults with CHD in the lowest risk group (Table 6 of Task Force #1), routine cardiac follow-up is recommended every three to five years as a rule.

The larger group of adults with moderate and complex CHD (Tables 4 and 5 of Task Force #1) requires more frequent follow-up, generally every 12 to 24 months. Such evaluation should include a detailed history and clinical

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examination. Diagnostic studies should be standardized, with performance of more extensive evaluations (e.g., cardiopulmonary/metabolic stress testing, cardiac MRI, cardiac catheterization) based on the individual patient's clinical course and findings. Part of such evaluations should include the detection of any new or progressive cardiac problems, patient education, and education of the primary care physician.

Finally, a smaller group of adults with CHD with complex anatomy and physiology require serial follow-up and examination at a regional ACHD center every 6 to 12 months, if not more frequently. This patient group includes adult patients with conditions such as single ventricle physiology, a morphologic right ventricle functioning in the systemic circuit, recalcitrant heart failure, recurring arrhythmias, and pulmonary vascular obstructive disease.

URGENT/EMERGENCY CARE

Most adults with CHD should wear medical alert devices and/or carry on their persons information that focuses on issues such as major diagnoses, the use of prosthetic valves or devices, anticoagulation, or other key points.

Emergency medical personnel at regional ACHD centers must be able to provide acute care for adults with CHD. The following situations and conditions go beyond the routine competence of many ER physicians and surgeons: intracardiac or intravascular shunts, pulmonary vascular disease, right ventricular dysfunction, and high-risk pregnancy.

Hospitalization for medical or cardiac acute care. Adults with moderate or severe CHD will usually require transfer to a regional ACHD center for urgent or acute care. This group includes patients with:

- Important intracardiac shunting;
- Greater than "mild" pulmonary vascular disease;
- Greater than "moderate" left ventricular or "mild" right ventricular dysfunction or failure;
- A systemic right ventricle;
- Single ventricle physiology;
- Greater than "mild" obstructive intracardiac valvular or vascular disease, including peripheral pulmonary artery stenosis or aortic coarctation, and excluding isolated aortic valve and many isolated mitral valve patients;
- Important congenital coronary arterial abnormalities;
- Pregnancy in the setting of important CHD;
- New onset of symptomatic tachyarrhythmias requiring institution of antiarrhythmic medication or ablation therapy, or bradyarrhythmias that include AV block or symptomatic sinus node dysfunction, in any of the patients listed above, repaired or unrepaired.

Patients with milder forms of CHD can usually receive their in-patient care in their community, sometimes in consultation with the specialized ACHD regional center. Representative examples include:

- Minimal residual intracardiac/vascular shunting with good ventricular function
- ASD, VSD, PDA corrected with good hemodynamic result
- New onset of symptomatic tachyarrhythmias requiring institution of antiarrhythmic medication or ablation therapy, or bradyarrhythmias that include AV block or symptomatic sinus node dysfunction, in patients with well-repaired ASD, VSD, or AV septal defect.

Non-emergent hospitalization should be based on the same general principles outlined above. Patients with moderate and complex lesions will often require longer and more costly admissions than other types of patients.

INTERVENTIONS

The increasing complexity and procedural requirements for adults with CHD is reflected in their greater than 60% prevalence of prior cardiac operations and their nearly 50% need for re-operation or interventional therapy at some point during adulthood. A review of hospitalizations over the past five years in one center with particular expertise in catheterization of adults with CHD revealed that 26% are non-procedural, 57% involve catheterization and 17% involve surgery. The unique and increasingly complex needs of adults with CHD mandates centralization of procedural care.

TREATMENT OUTCOMES

The evaluation of structure and process requires that the best approach be determined. Ideally, this determination should be based on strong evidence. Expert consensus is necessary when evidence is lacking, but it should not be considered a fair substitute for rigorously performed clinical studies. The field of ACHD faces substantial challenges in generating the evidence needed to define what the "best practices" are. Patient groups are heterogeneous both between and within disease categories. The numbers of patients within particular categories of CHD tend to be small. The need for long-term follow-up in assessing clinical outcomes will delay the evaluation of the effects of new technologies and treatments.

The measurement of outcomes is an appropriate indicator of quality because it is the composite result of what is achieved with both structure and process. Outcomes should be systematically tracked, evaluated, and improved; and outcome data can be used to identify opportunities to improve practice.

Caregivers for adults with CHD, in coordination with third-party payers and regulators of access to health care, have a unique opportunity to construct and effectively utilize data sources, in concert with other non-caregiver-established databases (e.g., Medicare). In such a fashion, questions asked by patient advocacy groups, caregivers, and payer/insurers concerning optimal care strategies and esti-

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mates of resource needs and utilization can be effectively addressed.

RECOMMENDATIONS

- Care of adults with CHD should be coordinated by regional ACHD centers that represent a resource for the medical community.
- An individual primary caregiver or cardiologist without specific training and expertise in adult CHD should manage adults with moderate and complex CHD only in collaboration with a physician with advanced training and experience in caring for adults with CHD.
- Every academic adult cardiology/cardiac surgery center should have access to a regional ACHD center for consultation and referral.
- Every cardiologist should have a referral relationship with a regional ACHD center.
- Approximately one regional ACHD center should be created to serve a population of 5 to 10 million people, with 30 to 50 such centers in the U.S.
- Within a single urban center, institutions should establish collaborative relationships.
- Each pediatric cardiology program should identify the ACHD center to which the transfer of patients will be made.
- An ACHD specialist should evaluate all adults with moderate and complex CHD at least once. The initial ACHD evaluation allows stratification of these patients according to risk and management difficulty.
- Adults with moderate and complex CHD will require regular evaluations at a regional ACHD center and will benefit from maintaining contact with a primary care physician.
- For adults with CHD in the lowest risk group (simple CHD), cardiac follow-up is recommended at least every three to five years. The larger group of adults with moderate and complex CHD will require more frequent follow-up, generally every 12 to 24 months. A smaller group of adults with very complex or unstable CHD will require follow-up at a regional ACHD center at a minimum of every 6 to 12 months.
- Every adult with CHD should have a primary care physician. To ensure communication, current clinical records should be on file both at a regional ACHD center and with the primary care provider (patients should also have copies of relevant records).
- All emergency care facilities should have an affiliation with a regional ACHD center.
- Patients with moderate or complex CHD require admission or transfer to a regional ACHD center for urgent or acute care.
- Most cardiac catheterization and electrophysiology procedures for adults with moderate and complex CHD should be performed in a regional ACHD center with appropriate experience in CHD, and in a laboratory with appropriate personnel and equipment. After consultation with staff in regional ACHD centers, it may be appropriate for local centers to perform such procedures.
- Surgical procedures in adults with CHD as outlined in Tables 4 and 5 of Task Force #1 should generally be performed in a regional ACHD center with specific excellence in the surgical care of CHD.
- Each regional ACHD center should participate in a medical and surgical database aimed at defining and improving outcomes in adults with CHD.
- Each regional ACHD center should encourage all ACHD patient data to be included in a national CHD database. Programs should work collaboratively on multicenter projects and develop investigator-initiated research proposals dealing with ACHD.
- The American College of Cardiology should recommend to the NHLBI and/or Agency for Health Care Research and Quality the formation of adult congenital centers for documenting and improving outcomes, education, and research.
- Each regional ACHD center should establish or affiliate with a patient advocacy group.

Task Force 5: Adults With Congenital Heart Disease: Access to Care

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INTRODUCTION

Access to optimal, specialized, appropriate health care, health and life insurance, and full employment remains a problem for many adolescent and adult patients with congenital heart disease (CHD) (1).

Health insurance may be difficult to obtain in adulthood because of "pre-existing conditions"—despite recent federal legislation—and because of uncertainties and misconceptions about the cost of care for adults with CHD. The actual costs of medical care appear to be relatively low in these patients compared with survivors of other chronic diseases

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#29
Andrea Brisbin – Trident Health System

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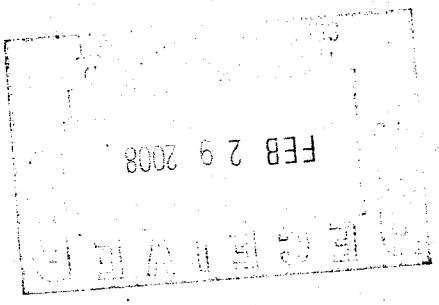
February 29, 2008

Via Hand Delivery
Gerald A. Wilson, M.D., Chairman
S.C. State Health Planning Committee
S.C. Department of Health & Environmental Control
Division of Planning & Certification of Need
2600 Bull Street
Columbia, S.C. 29201



Re: Draft 2008-2009 State Health Plan

Dear Dr. Wilson:

On behalf of Trident Health System, please accept this letter as its additional comments on the *draft 2008-2009 State Health Plan* ("*draft Plan*"). We appreciate the opportunity to comment on the *draft Plan* and we welcome any questions you may have concerning our positions.

Radiosurgery (Gamma Knife)

It is our understanding that oral and written comments have been submitted to the Committee advocating that additional language be inserted into the Radiosurgery section that gives preference to "teaching hospitals." Specifically, it has been requested that in considering a CON application of a health care facility for the acquisition and operation of a Gamma Knife, the Department must give preference to applicants that qualify as "teaching hospitals." This preference is neither clinically supportable nor is consistent with the express goals of the CON Act.

As background, we note that the *draft 2007 State Health Plan* included a similar standard giving a preference to applicants that qualify as "teaching hospitals." After receiving comments objecting to that criterion, the Department and the Committee correctly omitted it from the *draft 2008-2009 Plan.*

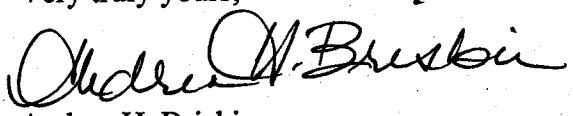
Although the term "teaching hospital" conceivably could include all hospitals in the state which offer or work in conjunction with one or more residency programs, the reality is that any

definition proposed would unnecessarily and unjustifiably restrict this proposed preference to an extremely small number of facilities in South Carolina. Ultimately, the definition of "teaching hospital" is an irrelevant issue because current data demonstrate that existing Gamma Knife surgery programs throughout the country have been successful at ***all*** types of institutions, regardless of whether they are public or private, profit or non-profit, or affiliated with an academic institution. As the Department is well aware, more than 2,500 scientific articles have been published confirming the efficacy of Gamma Knife surgery and none supports the requirement or preference that Gamma Knife surgery be performed at a "teaching hospital" or otherwise in an academic environment. Rather, the focus has been and must be on ensuring geographic accessibility to patients, the comprehensiveness of complementary oncology services to maximize the convenience to patients, the willingness of neurosurgeons to perform surgery at the institution, and the institution's open medical staff to allow any qualified neurosurgeon trained in Gamma Knife surgery to perform procedures. These characteristics can be and have been achieved at any type of institution, regardless of whether it qualifies as a "teaching hospital." Moreover, a preference for "teaching hospitals" imposes a limitation that necessarily will restrict the provision of Gamma Knife services to certain institutions in the State, which in turn will restrict valid competition and undermine the goal of increasing accessibility to South Carolina citizens.

Trident Health System appreciates the opportunity to provide these comments for the Department's consideration. Should you have any questions, please do not hesitate to contact me.

With best regards, I am

Very truly yours,



Andrea H. Brisbin

cc: Terry Gunn, FACHE
President, HCA Carolina Market
CEO, Trident Health System

#30
Doug White – Grand Strand Regional Medical Center

Grand Strand Regional Medical Center

809 82nd Parkway
Myrtle Beach, SC 29572
(843) 692-1000

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February 29, 2008

Via Hand Delivery

Gerald A. Wilson, M.D., Chairman
S.C. State Health Planning Committee
S.C. Department of Health & Environmental Control
Division of Planning & Certification of Need
2600 Bull Street
Columbia, S.C. 29201

Re: Draft 2008-2009 State Health Plan

Dear Dr. Wilson:

Please accept this letter as Grand Strand Regional Medical Center's comments on the *draft 2008-2009 State Health Plan* ("*draft Plan*"). On behalf of Grand Strand, we appreciate the opportunity comment on the following areas of interest and welcome any questions you may have concerning our positions.

Emergency Hospital Services

Grand Strand objects to the *draft Plan's* elimination of Standard 4, which currently requires a hospital wishing to operating a freestanding (off-campus) emergency service to establish such a service at a location that is greater than 30 miles from an existing hospital emergency department or off-campus emergency service. Because such a service necessarily is an extension of an existing hospital, Standard 4 serves the purposes of ensuring that there is no unnecessary duplication of emergency services, that patients are not caught in the middle of competing hospitals vying for emergency patient transfers, and that there remains a cohesive health care planning policy that enables the Department and health care providers to meaningfully measure facility-specific service areas and patient need.

Standard 4 was first adopted by the Department in the *2001 State Health Plan*, when the Department first established separate criteria for a hospital to obtain a certificate of need to establish an off-campus emergency department. Significantly, in order to ensure that a hospital did not duplicate either its own or other hospitals' emergency department services, Standard 4 has prohibited a hospital from establishing an off-campus emergency service within 30 miles of its own on-campus or off-campus emergency department, as well as the emergency departments of other hospitals. With the recent trend of both physicians and hospital systems establishing numerous urgent care centers throughout the State, Grand Strand firmly believes that the rationale advanced by other providers to advocate the elimination of the 30-mile rule—*i.e.*, that hospital emergency departments in South Carolina are overutilized and that the ability to construct new ED's close to other hospitals will cure this problem—is insupportable.

Moreover, the elimination of Standard 4 will have an unacceptably negative impact on patient care. In adopting Standard 4, the Department correctly recognized the potential dangers of allowing one hospital to set up its off-campus emergency department in close proximity to its competing hospital's campus. Specifically, under this scenario, a hospital's off-campus emergency department will have a greater economic incentive to transfer the patient to its main campus, although the competing hospital's campus is closer and the patient almost always is better served by being transferred to the closest hospital.

Accordingly, Grand Strand recommends that the Department retain Standard 4 in the *2008-2009 Plan*. Alternatively, if the 30-mile rule is eliminated, then Grand Strand requests that the Standard 4 proposed in the *draft Plan* (currently Standard 5 in the *2004-2005 Plan*) be amended as reflected in the following underlined language:

> 4. An off-campus emergency service must have written agreements with Emergency Medical Services providers and surrounding hospitals regarding serious medical problems, which the off-campus emergency service cannot handle. <u>For any case in which a patient is transferred from the off-campus emergency service, it must transfer the patient to the geographically closest hospital having the capacity to treat the patient.</u>

<u>Radiotherapy:</u>
<u>Specialized LINAC Capacity</u>

We commend the Committee's and the Department's efforts to update the radiotherapy and radiosurgery component of the *Plan* to reflect the quickly evolving state of this technology. We further support the *draft Plan's* recognition that certain linear accelerators providing specialized treatments (such as total body irradiation, IMRT, treatment of children, or via a Cyberknife) will have lesser clinical capacity than a standard linear accelerator.

However, we believe that the *draft Plan* adds language to the end of the Radiotherapy narrative section on Page II-60 which is inaccurate and needs to be clarified. Specifically, the *draft Plan* states that "[a]t this time, ***<u>the</u> linear accelerators at MUSC*** and the Cyberknife at Roper Hospital (CON 8-10-06) are determined to meet this definition and the need calculations for their service area have been adjusted accordingly." (Emphasis added.) It is our understanding, however, that MUSC operates at least four (4) linear accelerators, only one of which was designated in 2005 to provide pediatric and other "time-sensitive" procedures upon the issuance of CON SC-05-45. It is unclear whether the other three linear accelerators are utilized as anything other than standard linear accelerators with annual clinical capacity of 7,000 treatments. Thus, the *draft Plan* inaccurately designates ***all*** of MUSC's linear accelerators as utilizing "highly specialized techniques" and only having an annual clinical capacity of 4,000 treatments.

In order for the health care providers in the State to have meaningful notice of the clinical capacities and current utilization of radiotherapy modalities, the *Plan* must specifically identify ***each*** linear accelerator approved for operation in the State which it considers to have a 4000-treatment annual clinical capacity ***and*** the basis for such designation (*e.g.*, representations made in CON applications submitted by the provider, nature of modality such as a Cyberknife, etc.) Alternatively, if such information is not provided, we recommend that the entire sentence quoted above be deleted from the final *2008-2009 Plan*.

PET & PET/CT

The *draft Plan* continues to appropriately recognize that PET/CT imaging has virtually replaced stand-alone PET imaging for most uses and that PET and PET/CT modalities are interchangeable for purposes of CON standards and review. The *draft Plan* further continues to reflect the Department's view that the addition of a CT component to an existing PET service is not a new service that would trigger CON review. However, additional language in the *2004-2005 Plan* and the *draft Plan*, and the Department's practice in applying that language, effectively undermine this view. Specifically, Page II-69 of the *draft Plan* states that "The addition of a CT component to an existing PET service is not considered to be a new service that would trigger CON review, ***although it could still be subject to review because of equipment cost.***" (Emphasis added.) The Department has applied this language to require CON review of a project that replaces an existing PET service with a PET/CT service if the total project cost exceeds $600,000. However, as a matter of industry practice, a physically separate CT component is never "added" to an existing PET unit; rather, manufacturers simply sell a PET/CT unit to replace and/or trade in the existing PET unit. Because of this industry practice, and because the total project cost of a PET/CT unit will almost always exceed $600,000, a provider can never realistically obtain an exemption to replace its existing PET with a PET/CT. This cannot be what the Department intended when it adopted the view that PET and PET/CT were interchangeable services.

Accordingly, Grand Strand recommends that the above-quoted sentence is amended as follows:

The addition of a CT component to an existing PET service is not considered to be a new service that would trigger CON review and is considered to be the replacement of like equipment with similar capabilities with the meaning of the Department's regulations.~~, although it could still be subject to review because of equipment cost.~~

Grand Strand Regional Medical Center appreciates the opportunity to provide these comments for the Department's consideration. Should you have any questions, please do not hesitate to contact me.

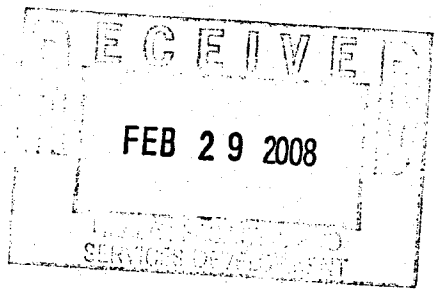
Sincerely,

Doug White
Chief Executive Officer

#31
Patricia "P.J." Johnson – Summerville Medical Center

Life is a gift. Live it *well.*

Summerville
Medical Center
A Facility of Trident Medical Center



February 29, 2008

Via Hand Delivery

Gerald A. Wilson, M.D., Chairman
S.C. State Health Planning Committee
S.C. Department of Health & Environmental Control
Division of Planning & Certification of Need
2600 Bull Street
Columbia, S.C. 29201

Re: Draft 2008-2009 State Health Plan

Dear Dr. Wilson:

Please accept this letter as Summerville Medical Center's comments on the *draft 2008-2009 State Health Plan* ("*draft Plan*"). On behalf of Summerville Medical Center, we appreciate the opportunity comment on the following areas of interest and welcome any questions you may have concerning our positions.

Emergency Hospital Services

Summerville Medical Center objects to the *draft Plan's* elimination of Standard 4, which currently requires a hospital wishing to operating a freestanding (off-campus) emergency service to establish such a service at a location that is greater than 30 miles from an existing hospital emergency department or off-campus emergency service. Because such a service necessarily is an extension of an existing hospital, Standard 4 serves the purposes of ensuring that there is no unnecessary duplication of emergency services, that patients are not caught in the middle of competing hospitals vying for emergency patient transfers, and that there remains a cohesive health care planning policy that enables the Department and health care providers to meaningfully measure facility-specific service areas and patient need.

Standard 4 was first adopted by the Department in the *2001 State Health Plan*, when the Department first established separate criteria for a hospital to obtain a certificate of need to establish an off-campus emergency department. Significantly, in order to ensure that a hospital did not duplicate either its own or other hospitals' emergency department services, Standard 4 has prohibited a hospital from establishing an off-campus emergency service within 30 miles of

its own on-campus or off-campus emergency department, as well as the emergency departments of other hospitals. With the recent trend of both physicians and hospital systems establishing numerous urgent care centers throughout the State, Summerville Medical Center firmly believes that the rationale advanced by other providers to advocate the elimination of the 30-mile rule—*i.e.*, that hospital emergency departments in South Carolina are overutilized and that the ability to construct new ED's close to other hospitals will cure this problem—is insupportable.

Moreover, the elimination of Standard 4 will have an unacceptably negative impact on patient care. In adopting Standard 4, the Department correctly recognized the potential dangers of allowing one hospital to set up its off-campus emergency department in close proximity to its competing hospital's campus. Specifically, under this scenario, a hospital's off-campus emergency department will have a greater economic incentive to transfer the patient to its main campus, although the competing hospital's campus is closer and the patient almost always is better served by being transferred to the closest hospital.

Accordingly, Summerville Medical Center recommends that the Department retain Standard 4 in the *2008-2009 Plan.* Alternatively, if the 30-mile rule is eliminated, then Summerville Medical Center requests that the Standard 4 proposed in the *draft Plan* (currently Standard 5 in the *2004-2005 Plan*) be amended as reflected in the following underlined language:

> 4. An off-campus emergency service must have written agreements with Emergency Medical Services providers and surrounding hospitals regarding serious medical problems, which the off-campus emergency service cannot handle. <u>For any case in which a patient is transferred from the off-campus emergency service, it must transfer the patient to the geographically closest hospital having the capacity to treat the patient.</u>

<u>*Radiotherapy:*</u>
<u>*Specialized LINAC Capacity*</u>

We commend the Committee's and the Department's efforts to update the radiotherapy and radiosurgery component of the *Plan* to reflect the quickly evolving state of this technology. We further support the *draft Plan's* recognition that certain linear accelerators providing specialized treatments (such as total body irradiation, IMRT, treatment of children, or via a Cyberknife) will have lesser clinical capacity than a standard linear accelerator.

However, we believe that the *draft Plan* adds language to the end of the Radiotherapy narrative section on Page II-60 which is inaccurate and needs to be clarified. Specifically, the *draft Plan* states that "[a]t this time, ***<u>the</u> linear accelerators at MUSC*** and the Cyberknife at Roper Hospital (CON 8-10-06) are determined to meet this definition and the need calculations for their service area have been adjusted accordingly." (Emphasis added.) It is our understanding, however, that MUSC operates at least four (4) linear accelerators, only one of which was designated in 2005 to provide pediatric and other "time-sensitive" procedures upon the issuance of CON SC-05-45. It is unclear whether the other three linear accelerators are utilized as anything other than standard linear accelerators with annual clinical capacity of 7,000 treatments. Thus, the *draft Plan* inaccurately designates ***all*** of MUSC's linear accelerators as utilizing "highly specialized techniques" and only having an annual clinical capacity of 4,000 treatments.

In order for the health care providers in the State to have meaningful notice of the clinical capacities and current utilization of radiotherapy modalities, the *Plan* must specifically identify ***each*** linear accelerator approved for operation in the State which it considers to have a 4000-treatment annual clinical capacity ***and*** the basis for such designation (*e.g.*, representations made in CON applications submitted by the provider, nature of modality such as a Cyberknife, etc.) Alternatively, if such information is not provided, we recommend that the entire sentence quoted above be deleted from the final *2008-2009 Plan.*

PET & PET/CT

The *draft Plan* continues to appropriately recognize that PET/CT imaging has virtually replaced stand-alone PET imaging for most uses and that PET and PET/CT modalities are interchangeable for purposes of CON standards and review. The *draft Plan* further continues to reflect the Department's view that the addition of a CT component to an existing PET service is not a new service that would trigger CON review. However, additional language in the *2004-2005 Plan* and the *draft Plan*, and the Department's practice in applying that language, effectively undermine this view. Specifically, Page II-69 of the *draft Plan* states that "The addition of a CT component to an existing PET service is not considered to be a new service that would trigger CON review, ***although it could still be subject to review because of equipment cost.***" (Emphasis added.) The Department has applied this language to require CON review of a project that replaces an existing PET service with a PET/CT service if the total project cost exceeds $600,000. However, as a matter of industry practice, a physically separate CT component is never "added" to an existing PET unit; rather, manufacturers simply sell a PET/CT unit to replace and/or trade in the existing PET unit. Because of this industry practice, and because the total project cost of a PET/CT unit will almost always exceed $600,000, a provider can never realistically obtain an exemption to replace its existing PET with a PET/CT. This cannot be what the Department intended when it adopted the view that PET and PET/CT were interchangeable services.

Accordingly, Summerville Medical Center recommends that the above-quoted sentence is amended as follows:

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Summerville Medical Center appreciates the opportunity to provide these comments for the Department's consideration. Should you have any questions, please do not hesitate to contact me.

Sincerely,

PJ Johnson

Patricia "P.J." Johnson, FACHE
Chief Executive Officer

#32
Terry Gunn – Trident Health System

Life is a gift. Live it *well.*

Trident Health System

Via Hand Delivery

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SERVICES DEVELOPMENT

February 29, 2008

Gerald A. Wilson, M.D., Chairman
S.C. State Health Planning Committee
S.C. Department of Health & Environmental Control
Division of Planning and Certification of Need
2600 Bull Street
Columbia, S.C. 29201

Re: Draft 2008-2009 State Health Plan

Dear Dr. Wilson:

Please accept this letter as Trident Medical Center's comments on the *draft 2008-2009 State Health Plan* ("*draft Plan*"). On behalf of Trident Medical Center, we appreciate the opportunity comment on the following areas of interest and welcome any questions you may have concerning our positions.

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Trident objects to the *draft Plan's* elimination of Standard 4, which currently requires a hospital wishing to operating a freestanding (off-campus) emergency service to establish such a service at a location that is greater than 30 miles from an existing hospital emergency department or off-campus emergency service. Because such a service necessarily is an extension of an existing hospital, Standard 4 serves the purposes of ensuring that there is no unnecessary duplication of emergency services, that patients are not caught in the middle of competing hospitals vying for emergency patient transfers, and that there remains a cohesive health care planning policy that enables the Department and health care providers to meaningfully measure facility-specific service areas and patient need.

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Specialized LINAC Capacity

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Sincerely,

Terry Gunn, FACHE
President, Carolina Market
CEO, Trident Health System

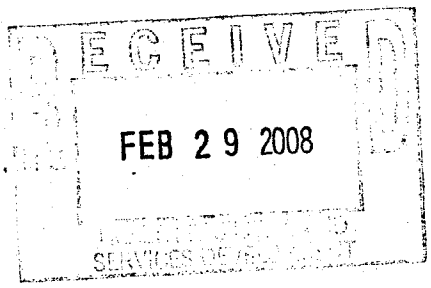
#33
Mitchell Mongell – Colleton Medical Center

Life is a gift. Live it *well.*

Colleton
Medical Center

February 29, 2008

Via Hand Delivery



Gerald A. Wilson, M.D., Chairman
S.C. State Health Planning Committee
S.C. Department of Health & Environmental Control
Division of Planning & Certification of Need
2600 Bull Street
Columbia, S.C. 29201

Re: Draft 2008-2009 State Health Plan

Dear Dr. Wilson:

Please accept this letter as Colleton Medical Center's comments on the *draft 2008-2009 State Health Plan* ("*draft Plan*"). On behalf of Colleton Medical Center, we appreciate the opportunity comment on the following areas of interest and welcome any questions you may have concerning our positions.

Emergency Hospital Services

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the rationale advanced by other providers to advocate the elimination of the 30-mile rule—*i.e.*, that hospital emergency departments in South Carolina are over utilized and that the ability to construct new ED's close to other hospitals will cure this problem—is insupportable.

Moreover, the elimination of Standard 4 will have an unacceptably negative impact on patient care. In adopting Standard 4, the Department correctly recognized the potential dangers of allowing one hospital to set up its off-campus emergency department in close proximity to its competing hospital's campus. Specifically, under this scenario, a hospital's off-campus emergency department will have a greater economic incentive to transfer the patient to its main campus, although the competing hospital's campus is closer and the patient almost always is better served by being transferred to the closest hospital.

Accordingly, Colleton Medical Center recommends that the Department retain Standard 4 in the *2008-2009 Plan*. Alternatively, if the 30-mile rule is eliminated, then Colleton Medical Center requests that the Standard 4 proposed in the *draft Plan* (currently Standard 5 in the *2004-2005 Plan*) be amended as reflected in the following underlined language:

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Specialized LINAC Capacity</u>

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However, we believe that the *draft Plan* adds language to the end of the Radiotherapy narrative section on Page II-60 which is inaccurate and needs to be clarified. Specifically, the *draft Plan* states that "[a]t this time, ***<u>the</u> linear accelerators at MUSC*** and the Cyberknife at Roper Hospital (CON 8-10-06) are determined to meet this definition and the need calculations for their service area have been adjusted accordingly." (Emphasis added.) It is our understanding, however, that MUSC operates at least four (4) linear accelerators, only one of

which was designated in 2005 to provide pediatric and other "time-sensitive" procedures upon the issuance of CON SC-05-45. It is unclear whether the other three linear accelerators are utilized as anything other than standard linear accelerators with annual clinical capacity of 7,000 treatments. Thus, the *draft Plan* inaccurately designates ***all*** of MUSC's linear accelerators as utilizing "highly specialized techniques" and only having an annual clinical capacity of 4,000 treatments.

In order for the health care providers in the State to have meaningful notice of the clinical capacities and current utilization of radiotherapy modalities, the *Plan* must specifically identify ***each*** linear accelerator approved for operation in the State which it considers to have a 4000-treatment annual clinical capacity ***and*** the basis for such designation (*e.g.*, representations made in CON applications submitted by the provider, nature of modality such as a Cyberknife, etc.) Alternatively, if such information is not provided, we recommend that the entire sentence quoted above be deleted from the final *2008-2009 Plan.*

Colleton Medical Center appreciates the opportunity to provide these comments for the Department's consideration. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Mitchell P. Mongell
Chief Executive Officer

#34
Timothy Rogers – South Carolina Home Care Association

South Carolina
Home Care Association

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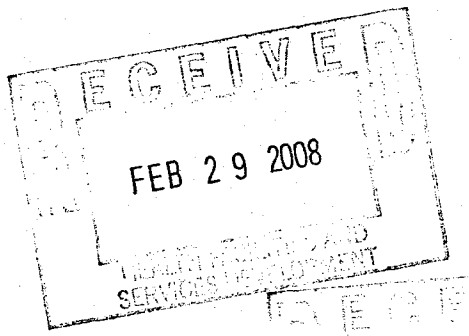

February 25, 2008

SC State Health Planning Committee
Division of Planning and Certification of Need
SC Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Dear Mr. Shelton and State Health Planning Committee Members:

On behalf of the South Carolina Home Care Association Board of Directors, I am writing to you in response to the Draft 2008-2009 South Carolina Health Plan. The SCHCA is a twenty six year old non-profit association that represents the Medicare/Medicaid certified home health care agencies in our state.

First of all, let me thank you for allowing us to submit comments. My comments concern the Home Health Agency section found in Chapter 2, Section E and specifically Standard Number 7 found on Page 120. This new standard provides for an exception to the Certification of Need process for an agency restricted to the service of pediatric patients.

Our Association and member agencies support a strong Certificate of Need process and believe that this planned approach has prevented our state from having an overgrowth of agencies that has been experienced by other states like Texas and Florida-who jointly have 25% of the Medicare-certified home health agencies in the nation. Excess agencies place an undue burden on state licensing and certification resources and negatively impact the quality of patient care provided.

While we understand that there are a limited number of home health agencies that serve the pediatric population due to many reasons such as specialty staff training requirements, the need for after hours/on call service, the stretching of an already nurse shortage, and payer reimbursement issues, we do not feel that this proposal provides enough oversight for the pediatric agencies. Therefore, the State of South Carolina would be better served with the language listed below.

We would recommend that the agencies be required to be Medicare-certified OR accredited through one of the three nationally recognized organizations that provide accreditation for home health agencies: The Joint Commission (JCAHO), the Community Health Accreditation Program (CHAP), and the Accreditation Commission for Health Care (ACHC). We also recommend that

that a Certificate of Need application be required for each county that the pediatric agency plans to serve rather than one application per agency. We further recommend incorporating the term "intermittent home health skilled nursing services" in this standard to make it consistent with the remainder of the State Health Plan section and with the nature of home health services.

Our Board of Directors, representing a diverse group of agencies across the Palmetto State and in concert with the American Academy of Pediatrics – South Carolina Chapter, recommends the following language inclusion in the State Health Plan:

Because of the limited number of home health providers available to treat children 14 years or younger, an exception to the above criteria may be made for a Certificate of Need for a Home Health Agency restricted to providing intermittent home health skilled nursing services to patients 14 years and younger. A Certificate of Need application will be required for each county in which an agency proposes to provide this specialized service to pediatric patients 14 years and younger. The applicant must document that no other agency offers this service in the county of application, and the agency will limit such services to the pediatric population 14 years and younger. The agency must be Medicare-certified or accredited through The Joint Commission, the Community Health Accreditation Program, or the Accreditation Commission for Health Care. The license for the agency will be restricted to serving children 14 years or younger and will ensure access to necessary and appropriate intermittent home health skilled nursing services to patients 14 years and younger. Any such approved agency will not be counted in the county need projections.

We thank you in advance for your consideration. If our Association can be of further assistance to you, please feel free to give me a call 919-848-3450.

Sincerely,

Jim Rogers

Timothy R. Rogers
Chief Executive Officer

#35
Jac Upfield – South Carolina Department of Mental Health

From: "Jaclynn Upfield" <JSU14@SCDMH.ORG>
To: <sheltolw@dhec.sc.gov>
Date: 3/3/2008 7:40 PM
Subject: Draft State Health Plan

Les,

Please forgive my tardiness in responding. The SCDMH inpatient program directors and hospital CEOs have reviewed the draft. There are a few comments and suggestions for revisions listed below.

1. Acute services for adults are limited to the beds that can be staffed. Crisis programs provide an alternative and work best when acute psychiatric inpatient beds for short stays for stabilization are also available in the community. Then limited state resources can be used to treat the more complicated severely and persistently mentally ill who need prolonged hospitalization. The underutilization of beds not in the state system seems to be exacerbated by the lack of funding for indigent patients.
2. Occupational therapy is not currently available to the children and adolescents in SCDMH. It is provided for the nursing home patients and adults as needed.
3. Our inpatient substance abuse treatment program for adults is primarily a residential facility, providing a structured therapeutic environment for a longer period of time than an acute program.

The draft encompasses our services quite adequately with the above comments.

If you have questions or need further information, please call or email me.

Jac Upfield

Jaclynn S. Upfield, MN, RN
Chief of Operations, Inpatient Services
SCDMH Systems Nurse
(803) 935-5761
NOTICE: This transmission may contain patient or other identifying information that is protected from disclosure by applicable federal and or state law. This communication is intended only for the use of the individual or entity named above. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copy of this communication is strictly prohibited and may subject the violator to civil and/or criminal penalties. If you have received this communication in error, please notify us immediately by telephone or by replying to this email and deleting all copies of this message and all attachments.

"There is nothing so well known as that we should not expect something for nothing--but we all do and call it Hope." -Edgar Howe

#36
Ronald Huffman – South Carolina Department of Social Services

DSS
Serving Children and Families

KATHLEEN M. HAYES, PH.D.
STATE DIRECTOR

MARK SANFORD
GOVERNOR

February 28, 2008

RECEIVED
MAR 4 2008

Mr. Les Shelton
Division of Planning and Certification of Need
S. C. Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Dear Mr. Shelton:

In reviewing the Draft 2008-2009 South Carolina State Health Plan, DSS believes it is necessary to delay finalization of the facility category of Residential Treatment Services for Children and Adolescents on pages II-90 through II-93.

Two factors are/will be impacting the number of beds identified in the draft. The first factor is the Certificate of Need (CON) waiver proviso that will allow high management group homes to seek licensure as a Residential Treatment Facility. As many as 12 facilities have notified DHHS of their intent to do so. We realize that not all of these facilities will follow through or meet the RTF standards but any increase in licensed facilities will result in more beds than allowed in the draft making it necessary to change the bed need methodology. In addition, due to the projected loss of Medicaid funding for non-RTF group treatment homes in January 2009, it may be in the best interest of the state to revise the RTF definition and criteria to allow a significant increase in the number and types or levels of RTF.

Another factor is that there is currently residential treatment facilities in South Carolina that primarily serve children from other States in CON beds intended for South Carolina children. This practice artificially skews the utilization of these beds. We recommend that some consideration be given to this issue within the standard, and request that SCDHEC consider these factors before finalizing this category.

We appreciate the opportunity to comment on the South Carolina Health Plan and look forward to your response.

Sincerely,

Ronald P. Huffman
Interim Director
Division of Human Services

RPH:bd

#37
Felicity Myers – South Carolina Department of Health and Human Services

State of South Carolina
Department of Health and Human Services

Mark Sanford
Governor

Emma Forkner
Director

March 6, 2008

Mr. Les Shelton
Division of Planning and Certification
SC Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Facsimile transmission: 803-545-4579

Dear Mr. Shelton:

I appreciate the opportunity to comment on the 2008-2009 South Carolina Health Plan that is used by the Certificate of Need (CoN) Program at the Department of Health and Environmental Control (DHEC). As the State Medicaid Agency, the South Carolina Department of Health and Human Services (DHHS) provides reimbursement for most of the services that are covered under the current CoN process. It is important for us to make you aware of current trends we have seen with some of these providers, and in some cases, to reflect our future plans for reimbursement.

General Comments

- Page I-4 – Change the acronym for the Centers for Medicare and Medicaid Services from *CMA* to *CMS*.

Nursing Facilities

- The more recent terminology used by CMS is *nursing facility* rather than *nursing home* and *resident* rather than *patient*.

- In South Carolina, we are currently funding more persons in Medicaid-sponsored long-term care in a community setting than in nursing facilities. Increasing options are now available through Medicaid home and community based waiver programs such as our Community Choice Waiver for the elderly and adults with disabilities, the Head and Spinal Cord Injury Waiver for these populations, and Programs for All-Inclusive Care of the Elderly (PACE).

Medical Services
P. O. Box 8206 Columbia South Carolina 29202-8206
(803) 898-2501 Fax (803) 255-8235

- SCDHHS is also actively engaged in a federal initiative, Money Follows the Person, to help transition persons who have been in a nursing facility for six months or more and desire to return to the community. While we expect these growth trends to continue in the provision of home care, it is also important to assure that we have nursing facility options available for our growing population in South Carolina to allow persons the opportunity to choose a care setting that best their needs. We urge the Department to carefully evaluate these trends in long term care in allocating CoNs statewide.

- SCDHHS has recently contracted with Thomson Medstat to produce a comprehensive long-term care data chartbook. The purpose of this chartbook is to provide our agency with information about long-term care programs and services in South Carolina and to serve as a basis for our future planning needs. We are currently reviewing a draft of this document and expect to have the final product completed by the end of this month. We would be happy to share a copy of this document with you once it is finalized.

- The information about home care options on page II-107, #2 should be updated. We will assist with that update if needed.

Hospice

- Hospice is one of the fastest growing services in our Medicaid long-term care continuum. DHHS is currently involved in an analysis of hospice growth and looking at alternatives to control rising expenditures. Because there is no current CoN process for hospice agencies, we have seen unprecedented growth statewide. We strongly urge DHEC to consider the need for a hospice CoN process.

Home Health

- We have been in discussion with providers and the provider association about pediatric home health service and ways to increase access and availability for this special population. We applaud the plan's interest in this sub-specialty and urge you to continue to give consideration to pediatric needs in the home health CoN process.

Psychiatric Residential Treatment Facilities

The 2007-2008 Appropriation Act included a temporary proviso to enable children's residential treatment services providers to obtain an exemption to the CoN process. The proviso requires that existing High Management Group Homes (HMGHs) may seek a CoN exemption to become Psychiatric Residential Treatment Facilities (PRTFs) by making the request to the DHEC prior to January 1, 2008. Twelve providers have requested this exemption through the DHEC.

- Currently, there are 413 licensed PRTF beds in South Carolina. If the 12 group homes that have requested a CON exemption convert all existing HMGH beds to PRTF beds, that will add over 600 new PRTF beds. Per DHEC, existing PRTF beds averaged 81.2% occupancy during fiscal year 2005-2006.

- If the proviso deadline is extended for an additional year, it will allow more HMGHs the opportunity to convert to PRTFs. This policy is in conflict with a waiver DHHS has to expand and develop community-based services to youth who meet the PRTF level of care. DHHS was recently awarded federal funds for 5 years to advance this initiative. This policy also contradicts the "Guiding Principles" developed in collaboration with child-serving state agencies for caring for SC children with emotional/behavioral problems. Research implicates community based services rather than institutional services as the most effective/efficient way to render services to this population. We urge DHEC to consider these factors when issuing any new CoNs and in determining the need for additional PRTF capacity.

I hope you will find these comments helpful in your considerations. If you have any questions, please contact Sam Waldrep at 803-898-2625. Mr. Waldrep can also assist you with any data that you need.

Sincerely,

Felicity Myers
Deputy Director

FM/wk